| | |
|---|---|
| Substance key: 000000803104 | Revision Date: 07/22/2019 |
| Version : 1 - 0 / CDN | Date of printing :07/22/2019 |

## SECTION 1. IDENTIFICATION

**Identification of the company:**
Clariant Plastics & Coatings Canada Inc.
2 Lone Oak Court
Toronto, Ontario, M9C 5R9
Telephone No.: +1 514-832-2559

**Information of the substance/preparation:**
BU Masterbatches
Product Stewardship, +1-704-331-7710
e-mail: SDS.NORAM@clariant.com

**Emergency tel. number:** +1 CANUTEC (613) 996-6666

**Trade name:** **RENOL-BLUE CV53800038-ZN**
**Material number:** CV53800038

**Chemical family:** Colourant preparation
Carrier: PVC

**Primary product use:** Additive for plastic material processing

## SECTION 2. HAZARDS IDENTIFICATION

**GHS classification in accordance with the Hazardous Products Regulations**

Not a hazardous substance or mixture.

**GHS label elements**

Not a hazardous substance or mixture.

**Other hazards**

Hazards Not Otherwise Classified:
If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical nature : Colourant preparation
Carrier: PVC

**Components**

| Chemical name | CAS-No. | Concentration (% w/w) |
|---|---|---|
| C.I. Pigment Blue 15:1 | 147-14-8 | 0.1 - 1 |
| Copper, [29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32]-, (1,3-dihydro-1,3-dioxo-2H-isoindol-2-yl)methyl derivs. | 68411-06-3 | 0.1 - 1 |
| Amorphous silicon dioxide | 7631-86-9 | 0.1 - 1 |
| Aluminium hydroxide | 21645-51-2 | 0.1 - 1 |

| | | |
|---|---|---|
| Calcium carbonate | 471-34-1 | 0.1 - 1 |
| Iron(III)oxide | 1309-37-1 | 1 - 5 |
| Di-n-octyltin-bis-(2-ethylhexylthioglycolate) | 15571-58-1 | 1 - 5 |
| C.I. Pigment White 6 | 13463-67-7 | 10 - 30 |
| Polyvinyl chloride | 9002-86-2 | 30 - 60 |

This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200) and by the Canadian WHMIS 2015 Hazardous Products Regulations (SOR/2015-17)., The hazardous ingredients of this product are encapsulated, therefore the material is not GHS classified for health and environmental hazards as exposure is not expected., Any concentration shown as a range is due to batch variation.

## SECTION 4. FIRST AID MEASURES

If inhaled : Move the victim to fresh air.
Give oxygen or artificial respiration if needed.
Get immediate medical advice/ attention.
Never give anything by mouth to an unconscious person.

In case of skin contact : Wash off immediately with plenty of water for at least 15 minutes.
In case of burns apply cold water until pain subsides then seek medical advice.
Burns must be treated by a physician.
If molten polymer contact the skin, cool rapidly with cold water. Do not attempt to peel polymer from skin. Obtain medical attention for thermal burn. Skin absorption of reground pellets is unlikely.

In case of eye contact : Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Get medical attention immediately if irritation develops and persists.

If swallowed : Rinse mouth.
Do NOT induce vomiting.
Never give anything by mouth to an unconscious person.
Get medical advice/ attention.

Most important symptoms and effects, both acute and delayed : The possible symptoms known are those derived from the labelling (see section 2).
No additional symptoms are known.

Notes to physician : Treat symptomatically.

## SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray
Foam
Carbon dioxide (CO2)

Dry chemical

| | | |
|---|---|---|
| Unsuitable extinguishing media | : | High volume water jet |
| Specific hazards during firefighting | : | In case of fire hazardous decomposition products may be produced such as:<br>Hydrogen chloride<br>Carbon monoxide<br>Carbon dioxide (CO2)<br>Nitrogen oxides (NOx)<br>Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.<br>Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces.<br>Metal oxides<br>Sulphur oxides |
| Further information | : | Combustible material<br>In the event of fire and/or explosion do not breathe fumes.<br>During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion<br>Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.<br>Do not allow run-off from fire fighting to enter drains or water courses.<br>Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. |
| Special protective equipment for firefighters | : | Wear an approved positive pressure self-contained breathing apparatus in addition to standard fire fighting gear. |

## SECTION 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Refer to protective measures listed in sections 7 and 8.<br>Avoid contact with skin, eyes and clothing.<br>Wash thoroughly after handling. |
| Environmental precautions | : | Do not allow contact with soil, surface or ground water.<br>Prevent product from entering drains. |
| Methods and materials for containment and cleaning up | : | Avoid dust formation.<br>Take measures to prevent the build up of electrostatic charge.<br>Sweep up and shovel into suitable containers for disposal.<br>Take up uncontaminated material and pass on for further processing.<br>After cleaning, flush away traces with water. |

## SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Take measures to prevent the build up of electrostatic charge.

Advice on safe handling : Handle in accordance with good industrial hygiene and safety practice.
Use only with adequate ventilation/personal protection.
For personal protection see section 8.
Avoid contact with skin, eyes and clothing.
Use only with adequate ventilation.
When handling hot melts use suitable protective clothing.
Avoid dust formation. Keep away from sources of ignition.
Lead off electrostatic charges.

Conditions for safe storage : Keep container tightly closed in a cool, well-ventilated place.
Protect from moisture.
Keep away from direct sunlight.

Further information on storage conditions : Store in a cool, dry, well-ventilated area. Keep container sealed when not in use.
Keep in an area equipped with sprinklers.
Minimize dust generation and accumulation.

Materials to avoid : not required

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Components with workplace control parameters**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|---|---|---|---|
| C.I. Pigment Blue 15:1 | 147-14-8 | TWA | 1 mg/m3 (Copper) | NIOSH REL |
| Copper, [29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32]-, (1,3-dihydro-1,3-dioxo-2H-isoindol-2-yl)methyl derivs. | 68411-06-3 | TWA | 1 mg/m3 (Copper) | NIOSH REL |
| Iron(III)oxide | 1309-37-1 | TWA (Respirable) | 5 mg/m3 | CA AB OEL |
| | | TWA (Fumes) | 5 mg/m3 (Iron) | CA BC OEL |
| | | TWA (Dust) | 5 mg/m3 (Iron) | CA BC OEL |
| | | STEL (Fumes) | 10 mg/m3 (Iron) | CA BC OEL |
| | | TWAEV (fume and | 5 mg/m3 (Iron) | CA QC OEL |

| | | | | |
|---|---|---|---|---|
| | | dust) | | |
| | | TWA (Respirable fraction) | 5 mg/m3 | ACGIH |
| Amorphous silicon dioxide | 7631-86-9 | TWA (Dust) | 20 Million particles per cubic foot (Silica) | OSHA Z-3 |
| | | TWA (Dust) | 80 mg/m3 / %SiO2 (Silica) | OSHA Z-3 |
| Polyvinyl chloride | 9002-86-2 | TWA (Respirable) | 1 mg/m3 | CA BC OEL |
| | | TWAEV (total dust) | 10 mg/m3 | CA QC OEL |
| | | TWA (Respirable fraction) | 1 mg/m3 | ACGIH |
| C.I. Pigment White 6 | 13463-67-7 | TWA | 10 mg/m3 | CA AB OEL |
| | | TWA (Total dust) | 10 mg/m3 | CA BC OEL |
| | | TWA (respirable dust fraction) | 3 mg/m3 | CA BC OEL |
| | | TWAEV (total dust) | 10 mg/m3 | CA QC OEL |
| Aluminium hydroxide | 21645-51-2 | TWAEV (total dust) | 10 mg/m3 | CA QC OEL |
| | | TWA (Respirable) | 1 mg/m3 (Aluminium) | CA BC OEL |
| | | TWA (Respirable fraction) | 1 mg/m3 (Aluminium) | ACGIH |
| Calcium carbonate | 471-34-1 | TWAEV (total dust) | 10 mg/m3 | CA QC OEL |

**Engineering measures** : Use only in area provided with appropriate exhaust ventilation.
Provide appropriate exhaust ventilation at machinery and at places where dust can be generated.
Use engineering controls such as local or general exhaust to maintain airborne concentrations below exposure limits.

**Personal protective equipment**

Respiratory protection : Use NIOSH/MSHA approved respirators following manufacturer's recommendations where dust or fume may be generated.
Use respiratory protective equipment when using this product at elevated temperatures (see section 8).

Hand protection
Remarks : Nitrile rubber gloves. Impervious butyl rubber gloves PVC

| | | |
|---|---|---|
| | | Neoprene gloves When handling hot material, use heat resistant gloves. |
| Eye protection | : | Safety glasses with side-shields |
| Skin and body protection | : | Wear protective clothing, including long sleeves and gloves, to prevent skin contact.<br>When handling hot melts use suitable protective clothing. |
| Hygiene measures | : | The usual Industrial Hygiene precautions must be taken during work, in particular: do not drink, eat or smoke during the handling of the product and clean hands and face during work intervals and after work. |

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|---|---|---|
| Appearance | : | Granules |
| Colour | : | blue |
| Odour | : | characteristic |
| Odour Threshold | : | Not applicable |
| pH | : | Not applicable |
| Melting point | : | > 70 °C |
| Boiling point | : | Not applicable |
| Flash point | : | Not applicable |
| Evaporation rate | : | Not applicable |
| Flammability (solid, gas) | : | not determined |
| Self-ignition | : | Not applicable |
| Upper explosion limit / upper flammability limit | : | not tested. |
| Lower explosion limit / Lower flammability limit | : | not tested. |
| Vapour pressure | : | Not applicable |
| Relative vapour density | : | Not applicable |
| Relative density | : | not available |
| Density | : | not tested. |

| | | |
|---|---|---|
| Solubility(ies) | | |
| Water solubility | : | insoluble |
| Partition coefficient: n-octanol/water | : | This property is not applicable for mixtures. |
| Decomposition temperature | : | > 200 °C |
| Viscosity | | |
| Viscosity, dynamic | : | Not applicable |
| Viscosity, kinematic | : | Not applicable |
| Explosive properties | : | no data available<br>no data available |
| Oxidizing properties | : | not available |
| Surface tension | : | Not relevant |
| Particle size | : | Product specific |

## SECTION 10. STABILITY AND REACTIVITY

| | | |
|---|---|---|
| Reactivity | : | No dangerous reaction known under conditions of normal use. |
| Chemical stability | : | Stable |
| Possibility of hazardous reactions | : | Lithium |
| Conditions to avoid | : | To avoid thermal decomposition, do not overheat.<br>Heating can release hazardous gases.<br>Keep away from heat, sparks, open flames, and other sources of ignition.<br>If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.<br>Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. |
| Incompatible materials | : | none<br>None.<br>Strong oxidizing agents |
| Hazardous decomposition products | : | Stable under recommended storage conditions.<br>When handled and stored appropriately, no dangerous decomposition products are known<br>The product does not contain any chemical groups which suggest self-reactive properties, nor is the estimated SADT |

less than 75 °C, nor is the exothermic decomposition energy higher than 300 J/g.
No decomposition if stored and applied as directed.

## SECTION 11. TOXICOLOGICAL INFORMATION

**Information on likely routes of exposure**

None known.

**Acute toxicity**

**Product:**

| | | |
|---|---|---|
| Acute dermal toxicity | : | Acute toxicity estimate: > 5,000 mg/kg<br>Method: Calculation method |

**Components:**

**C.I. Pigment Blue 15:1:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat, male and female): > 6,400 mg/kg<br>Method: OECD Test Guideline 401<br>GLP: no |
| Acute inhalation toxicity | : | Remarks: no data available |
| Acute dermal toxicity | : | LD50 (Rat, male): > 5,000 mg/kg<br>Method: OECD Test Guideline 402<br>GLP: no |
| Acute toxicity (other routes of administration) | : | LD50 (Mouse, male and female): > 2,000 mg/kg<br>Application Route: Intraperitoneal injection<br>Method: internal test<br>Test substance: other TS<br>GLP: no |

**Amorphous silicon dioxide:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat, male and female): > 5,000 mg/kg<br>Method: OECD Test Guideline 401<br>GLP: yes<br>Remarks: No significant adverse effects were reported |
| Acute inhalation toxicity | : | LC50 (Rat, male and female): > 2.08 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Method: OECD Test Guideline 403<br>GLP: yes<br>Assessment: The substance/mixture is not toxic on inhalation as defined by dangerous goods regulations. |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg<br>Method: Other<br>GLP: no |

**Aluminium hydroxide:**

Acute oral toxicity : LD50 (Rat, female): > 2,000 mg/kg
Method: OECD Test Guideline 423
GLP: yes
Remarks: No significant adverse effects were reported

Acute inhalation toxicity : LC50 (Rat, male and female): > 2.3 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
GLP: yes
Assessment: The substance/mixture is not toxic on inhalation as defined by dangerous goods regulations.
Remarks: By analogy with a product of similar composition

Acute dermal toxicity : Remarks: Not applicable

**Iron(III)oxide:**

Acute oral toxicity : LD50 (Rat, male): > 10,000 mg/kg
Method: Other
GLP: No information available.

Acute inhalation toxicity : LC0 (Rat, male): > 0.21 mg/l
Exposure time: 14 d
Method: OECD Test Guideline 412
GLP: yes

Acute dermal toxicity : Remarks: no data available

Acute toxicity (other routes of administration) : LD50 (Rat): 5,550 mg/kg
Application Route: Intraperitoneal injection

**Di-n-octyltin-bis-(2-ethylhexylthioglycolate):**

Acute oral toxicity : LD50 (Rat, male and female): 2,000 mg/kg
Method: OECD Test Guideline 401
GLP: yes

Acute inhalation toxicity : Remarks: Not applicable

Acute dermal toxicity : LD50 (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 402
GLP: yes

**C.I. Pigment White 6:**

Acute oral toxicity : LD50 (Rat, female): > 5,000 mg/kg
Method: OECD Test Guideline 425
GLP: no

Acute inhalation toxicity : LC50 (Rat, male and female): 3.4 - 5.1 mg/l

Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
GLP: no
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : Assessment: The substance or mixture has no acute dermal toxicity
Remarks: not required

**Polyvinyl chloride:**

Acute oral toxicity : Remarks: Not relevant

Acute inhalation toxicity : Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : Remarks: Not relevant

**Skin corrosion/irritation**

**Product:**

Result: No skin irritation

**Components:**

**C.I. Pigment Blue 15:1:**

Species: Rabbit
Exposure time: 20 h
Method: OECD Test Guideline 404
Result: No skin irritation
GLP: no

**Amorphous silicon dioxide:**

Species: Rabbit
Exposure time: 4 h
Method: OECD Test Guideline 404
Result: No skin irritation
GLP: yes

**Aluminium hydroxide:**

Species: Rabbit
Exposure time: 4 h
Method: OECD Test Guideline 404
Result: No skin irritation
GLP: yes

**Iron(III)oxide:**

Species: Rabbit
Exposure time: 4 h

Method: OECD Test Guideline 404
Result: No skin irritation
GLP: yes

**C.I. Pigment White 6:**

Species: Rabbit
Exposure time: 4 h
Method: OECD Test Guideline 404
Result: No skin irritation
GLP: no

**Polyvinyl chloride:**

Remarks: This information is not available.

**Serious eye damage/eye irritation**

**Product:**

Result: No eye irritation

**Components:**

**C.I. Pigment Blue 15:1:**

Species: Rabbit
Result: No eye irritation
Exposure time: 24 h
Method: OECD Test Guideline 405
GLP: no

**Amorphous silicon dioxide:**

Species: Rabbit
Result: No eye irritation
Exposure time: 24 h
Method: OECD Test Guideline 405
GLP: yes

**Aluminium hydroxide:**

Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
GLP: yes

**Iron(III)oxide:**

Species: rabbit eye
Result: No eye irritation
Exposure time: 192 h
Method: OECD Test Guideline 405
GLP: yes

**Di-n-octyltin-bis-(2-ethylhexylthioglycolate):**

Species: rabbit eye
Result: non-irritant
Exposure time: 96 h
Method: OECD Test Guideline 405
GLP: yes

**C.I. Pigment White 6:**

Species: rabbit eye
Result: No eye irritation
Method: OECD Test Guideline 405
GLP: No information available.

**Polyvinyl chloride:**

Remarks: This information is not available.

**Respiratory or skin sensitisation**

**Product:**

Result: non-sensitizing

**Components:**

**C.I. Pigment Blue 15:1:**

Test Type: Local lymph node assay (LLNA)
Exposure routes: Dermal
Species: Mouse
Method: OECD Test Guideline 429
Result: Not a skin sensitizer.
GLP: yes

Test Type: Maximisation Test
Exposure routes: Dermal
Species: Guinea pig
Method: OECD Test Guideline 406
Result: Not a skin sensitizer.
GLP: yes

**Amorphous silicon dioxide:**

Remarks: no data available

**Aluminium hydroxide:**

Test Type: Maximisation Test
Exposure routes: Dermal
Species: Guinea pig
Method: OECD Test Guideline 406
Result: Not a skin sensitizer.
GLP: yes

Test Type: Respiratory system
Exposure routes: inhalation (dust/mist/fume)
Species: Mouse
Method: Other
Result: Does not cause respiratory sensitisation.
GLP: no
Remarks: By analogy with a product of similar composition

**Iron(III)oxide:**

Test Type: Maurer optimisation test
Exposure routes: Skin contact
Species: Guinea pig
Method: Other
Result: Not a skin sensitizer.
GLP: No information available.

**Di-n-octyltin-bis-(2-ethylhexylthioglycolate):**

Test Type: Guinea pig maximization test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: May cause sensitisation by skin contact.
GLP: yes

**C.I. Pigment White 6:**

Test Type: Local lymph node assay (LLNA)
Exposure routes: Dermal
Species: Mouse
Method: OECD Test Guideline 429
Result: Not a skin sensitizer.
GLP: No information available.

Test Type: Buehler Test
Exposure routes: Dermal
Species: Guinea pig
Method: OECD Test Guideline 406
Result: Not a skin sensitizer.
GLP: yes

Test Type: Respiratory system
Exposure routes: inhalation (dust/mist/fume)
Species: Mouse
Method: Other
Result: Does not cause respiratory sensitisation.
GLP: No information available.

**Polyvinyl chloride:**

Exposure routes: Skin contact
Result: not known

**Germ cell mutagenicity**

**Components:**

**C.I. Pigment Blue 15:1:**

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Concentration: 20 - 10000 µg/plate
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: no

Test Type: Ames test
Test system: Salmonella typhimurium
Concentration: 25 - 5000 µg/plate
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: No information available.

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster cells
Concentration: 750 - 3000 µg/ml
Metabolic activation: with and without metabolic activation
Method: Other
Result: negative
GLP: No information available.

Test Type: In vitro mammalian cell gene mutation test
Test system: rat hepatocytes
Method: OECD Test Guideline 482
Result: negative
GLP: yes

Genotoxicity in vivo : Test Type: in vivo assay
Species: Mouse (male and female)
Strain: C57BL/6 x DBA/2
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 484
Result: negative
GLP: No information available.

Test Type: Micronucleus test
Species: Hamster (male and female)
Cell type: Bone marrow cells
Application Route: oral (gavage)
Exposure time: 48 h
Dose: 1250 - 2500 - 5000 mg/kg
Method: Other
Result: negative
GLP: No information available.

Germ cell mutagenicity - : In vivo tests did not show mutagenic effects, In vitro tests did

| | | |
|---|---|---|
| Assessment | | not show mutagenic effects |

**Amorphous silicon dioxide:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Ames test<br>Test system: Salmonella typhimurium<br>Concentration: 667 - 10000 µg/plate<br>Metabolic activation: with and without metabolic activation<br>Method: OECD Test Guideline 471<br>Result: negative<br>GLP: yes<br><br>Test Type: In vitro gene mutation study in mammalian cells<br>Test system: Chinese hamster ovary cells<br>Concentration: 10 - 500 µg/ml<br>Metabolic activation: with and without metabolic activation<br>Method: OECD Test Guideline 476<br>Result: negative<br>GLP: yes<br><br>Test Type: Chromosome aberration test in vitro<br>Test system: Chinese hamster ovary cells<br>Concentration: 38 - 1000 µg/ml<br>Metabolic activation: with and without metabolic activation<br>Method: OECD Test Guideline 473<br>Result: negative<br>GLP: yes |
| Genotoxicity in vivo | : | Test Type: Cytogenetic assay<br>Species: Rat (male)<br>Strain: Fischer F344<br>Application Route: Inhalation<br>Exposure time: 13 w, 6 h/d, 5 d/wk<br>Dose: ca. 50 mg/m3<br>Method: Other<br>Result: negative<br>GLP: No information available. |
| Germ cell mutagenicity - Assessment | : | In vitro tests did not show mutagenic effects, In vivo tests did not show mutagenic effects |

**Aluminium hydroxide:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: In vitro gene mutation study in mammalian cells<br>Test system: mouse lymphoma cells<br>Concentration: 5, 10, 20, 40, 60, 80, 100 an<br>Metabolic activation: with and without metabolic activation<br>Method: OECD Test Guideline 476<br>Result: negative<br>GLP: yes<br>Remarks: By analogy with a product of similar composition<br><br>Test Type: Chromosome aberration test in vitro<br>Test system: Human lymphocytes |

Concentration: 0, 5, 10, 15 and 25 µM AlCl3.
Metabolic activation: without
Method: OECD Test Guideline 473
Result: positive
GLP: No information available.
Remarks: By analogy with a product of similar composition

Test Type: In vitro gene mutation study in mammalian cells
Test system: mouse lymphoma cells
Concentration: 6.094, 12.19, 24.38, 48.75, 97
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: yes

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Rat (male and female)
Strain: Sprague-Dawley
Cell type: Bone marrow cells
Application Route: oral (gavage)
Exposure time: two doses (24 h)
Dose: 500 - 1000 - 2000 mg/kg
Method: OECD Test Guideline 474
Result: negative
GLP: yes

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

**Iron(III)oxide:**

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Concentration: 8 - 5000 µg/plate
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: No information available.
Remarks: By analogy with a product of similar composition

Test Type: HGPRT assay
Test system: V79 cells (embryonic lung fibroblasts) of the Chinese hamster
Concentration: 6 - 36 µg/ml
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: yes
Remarks: By analogy with a product of similar composition

Test Type: Chromosome aberration test in vitro
Test system: V79 cells (embryonic lung fibroblasts) of the Chinese hamster
Concentration: 6,25 - 25 µg/ml

Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: negative
GLP: yes
Remarks: By analogy with a product of similar composition

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Rat (male)
Strain: Sprague-Dawley
Application Route: oral (gavage)
Exposure time: 24 h
Dose: 3,75 mg/kg
Method: Other
Result: negative
GLP: No information available.

Germ cell mutagenicity - Assessment : It is concluded that the product is not mutagenic based on evaluation of several mutagenicity tests.

**Di-n-octyltin-bis-(2-ethylhexylthioglycolate):**

Genotoxicity in vitro : Test Type: In vitro gene mutation study in mammalian cells
Test system: mouse lymphoma cells
Concentration: 0,006 - 100 µg/ml
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: yes

Test Type: Ames test
Test system: Salmonella typhimurium
Concentration: 150 - 12150 µg/ml
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: no

Genotoxicity in vivo : Test Type: Chromosome Aberration Test
Species: Mouse (male and female)
Cell type: Bone marrow cells
Application Route: oral (gavage)
Exposure time: 30 h
Dose: 2250 - 4500 - 9000 mg/kg
Method: OECD Test Guideline 474
Result: negative
GLP: No information available.
Test substance: other TS

Test Type: Chromosome Aberration Test
Species: Mouse (male and female)
Strain: CD1
Cell type: Bone marrow cells
Application Route: oral (gavage)
Exposure time: 72 h

Dose: 2250 - 4500 - 9000 mg/kg
Method: OECD Test Guideline 474
Result: negative
GLP: No information available.
Test substance: other TS

Germ cell mutagenicity - Assessment : It is concluded that the product is not mutagenic based on evaluation of several mutagenicity tests.

**C.I. Pigment White 6:**

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Concentration: 333 - 5000 µg/plate
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: Ames test
Test system: Escherichia coli
Concentration: 333 - 5000 µg/plate
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse (male and female)
Strain: ICR
Cell type: Erythrocytes
Application Route: oral (gavage)
Exposure time: single treatment
Dose: 500 - 1000 - 2000 mg/kg
Method: OECD Test Guideline 474
Result: negative
GLP: yes

Germ cell mutagenicity - Assessment : In vitro tests did not show mutagenic effects, In vivo tests did not show mutagenic effects

**Polyvinyl chloride:**

Genotoxicity in vitro : Remarks: Not applicable

Germ cell mutagenicity - Assessment : No information available.

**Carcinogenicity**

**Components:**

**C.I. Pigment Blue 15:1:**

Carcinogenicity - : No information available.

Assessment

**Amorphous silicon dioxide:**

Species: Rat, (male and female)
Application Route: oral (feed)
Exposure time: 103 w
Dose: 1,25 - 2,5 - 5 % in diet
Group: yes
Frequency of Treatment: daily
NOAEL: ca. 1,800 - 3,000 mg/kg bw/day
Method: OECD Test Guideline 453
Result: negative
GLP: No information available.

Carcinogenicity - Assessment : Not classifiable as a human carcinogen.

**Aluminium hydroxide:**

Carcinogenicity - Assessment : Not classifiable as a human carcinogen.

**Iron(III)oxide:**

Species: Rat, (male and female)
Application Route: oral (gavage)
Exposure time: 798 d
Dose: 10 - 40 mg/kg
Group: yes
Frequency of Treatment: every other week
Method: Other
GLP: No information available.
Remarks: Based on available data, the classification criteria are not met.

Species: Rat, (male and female)
Application Route: Intraperitoneal injection
Exposure time: 790 - 914 d
Dose: 200 mg/kg
Group: yes
Frequency of Treatment: 3 injections; every 8 weeks
Method: Other
GLP: No information available.
Remarks: Based on available data, the classification criteria are not met.

Carcinogenicity - Assessment : Carcinogenicity classification not possible from current data.

**Di-n-octyltin-bis-(2-ethylhexylthioglycolate):**

Carcinogenicity - Assessment : No information available.

**C.I. Pigment White 6:**

Carcinogenicity - Assessment : Not classifiable as a human carcinogen.

**Polyvinyl chloride:**

Carcinogenicity - Assessment : No information available.

**Reproductive toxicity**

**Components:**

**C.I. Pigment Blue 15:1:**

Effects on fertility : Test Type: One generation study
Species: Rat, male and female
Strain: Sprague-Dawley
Application Route: oral (gavage)
Dose: 0, 40, 200, 1000 mg/kg bw/day
Duration of Single Treatment: > 46 d
General Toxicity - Parent: NOAEL: 1,000 mg/kg body weight
General Toxicity F1: NOAEL: 1,000 mg/kg body weight
Method: OECD Test Guideline 421
GLP: yes

Effects on foetal development : Test Type: reproductive and developmental toxicity study
Species: Rat, male and female
Strain: Sprague-Dawley
Application Route: oral (gavage)
Dose: 40, 200, 1000 mg/kg bw/day
Duration of Single Treatment: > 46 d
General Toxicity Maternal: NOAEL: 1,000 mg/kg body weight
Teratogenicity: NOAEL: 1,000 mg/kg body weight
Developmental Toxicity: NOAEL: 1,000 mg/kg body weight
Method: OECD Test Guideline 421
GLP: yes

Reproductive toxicity - Assessment : No evidence of adverse effects on sexual function and fertility, or on development, based on animal experiments.

**Amorphous silicon dioxide:**

Effects on fertility : Test Type: One generation study
Species: Rat, male and female
Strain: Sprague-Dawley
Application Route: oral (feed)
Dose: 497 (m), 509 (f) mg/kg
General Toxicity - Parent: NOAEL: 497 mg/kg body weight
General Toxicity F1: NOAEL: 497 mg/kg body weight
Method: OECD Test Guideline 415
GLP: no

Effects on foetal development : Test Type: Pre-natal
Species: Rat

Strain: wistar
Application Route: oral (gavage)
Dose: 13,5 - 62,7 - 292 - 1350mg/kg
General Toxicity Maternal: NOAEL: 1,350 mg/kg body weight
Teratogenicity: NOAEL: 1,350 mg/kg body weight
Method: OECD Test Guideline 414
GLP: no

Reproductive toxicity - Assessment : No evidence of adverse effects on sexual function and fertility, or on development, based on animal experiments.
No teratogenic effects to be expected.

**Aluminium hydroxide:**

Effects on fertility : Test Type: One generation study
Species: Rat, male and female
Strain: Sprague-Dawley
Application Route: Drinking water
Dose: 87 - 289 - 867 mg/kg
Duration of Single Treatment: 365 d
General Toxicity - Parent: NOAEL: ca. 867 mg/kg body weight
General Toxicity F1: NOAEL: ca. 87 mg/kg body weight
Method: Other
GLP: yes
Remarks: By analogy with a product of similar composition

Effects on foetal development : Test Type: Pre-natal
Species: Rat, female
Strain: wistar
Application Route: oral (gavage)
Dose: 66,5 - 133 - 266 mg/kg
Duration of Single Treatment: 10 d
Frequency of Treatment: 2 daily
General Toxicity Maternal: NOAEL: 266 mg/kg body weight
Teratogenicity: NOAEL: 266 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 266 mg/kg body weight
Method: OECD Test Guideline 414
GLP: No information available.

Reproductive toxicity - Assessment : No evidence of adverse effects on sexual function and fertility, or on development, based on animal experiments.

**Iron(III)oxide:**

Effects on fertility : Remarks: Not applicable

Effects on foetal development : Remarks: Not applicable

Reproductive toxicity - Assessment : No reproductive toxicity to be expected.
No teratogenic effects to be expected.

**Di-n-octyltin-bis-(2-ethylhexylthioglycolate):**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Two-generation study<br>Species: Rat, male and female<br>Strain: Sprague-Dawley<br>Application Route: oral (feed)<br>Dose: 20 - 60 -200 ppm<br>General Toxicity - Parent: NOAEL: ca. 1.6 mg/kg body weight<br>General Toxicity F1: NOAEL: 1.6 mg/kg body weight<br>Method: OECD Test Guideline 416<br>GLP: yes<br>Remarks: By analogy with a product of similar composition |
| Effects on foetal development | : | Species: Rabbit<br>Strain: New Zealand white<br>Application Route: oral (gavage)<br>Dose: 4 - 20 - 80 mg/kg<br>General Toxicity Maternal: NOAEL: 20 mg/kg body weight<br>Teratogenicity: NOAEL: 80 mg/kg body weight<br>Method: OECD Test Guideline 414<br>GLP: yes |
| Reproductive toxicity - Assessment | : | Clear evidence of adverse effects on development, based on animal experiments.<br>Classification as "teratogenic" is not justifiable. |

**C.I. Pigment White 6:**

| | | |
|---|---|---|
| Effects on fertility | : | Remarks: no data available |
| Effects on foetal development | : | Test Type: Pre-natal<br>Species: Rat, female<br>Strain: wistar<br>Application Route: oral (gavage)<br>Dose: 100, 300, 1000 mg/kg bw<br>Duration of Single Treatment: 14 d<br>Frequency of Treatment: 1 daily<br>General Toxicity Maternal: NOAEL: 1,000 mg/kg body weight<br>Developmental Toxicity: NOAEL: 1,000 mg/kg body weight<br>Embryo-foetal toxicity: NOEL: 1,000 mg/kg body weight<br>Method: OECD Test Guideline 414<br>GLP: yes<br>Remarks: No significant adverse effects were reported |
| Reproductive toxicity - Assessment | : | No evidence of adverse effects on sexual function and fertility, or on development, based on animal experiments.<br>Did not show teratogenic effects in animal experiments. |

**Polyvinyl chloride:**

| | | |
|---|---|---|
| Effects on fertility | : | Remarks: This information is not available. |
| Effects on foetal development | : | Remarks: This information is not available. |
| Reproductive toxicity - | : | No information available. |

Assessment No information available.

**STOT - single exposure**

**Components:**

**C.I. Pigment Blue 15:1:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

**Amorphous silicon dioxide:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

**Aluminium hydroxide:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

**Iron(III)oxide:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

**Di-n-octyltin-bis-(2-ethylhexylthioglycolate):**

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

**C.I. Pigment White 6:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

**Polyvinyl chloride:**

Remarks: no data available

**STOT - repeated exposure**

**Components:**

**C.I. Pigment Blue 15:1:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

**Amorphous silicon dioxide:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

**Aluminium hydroxide:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

**Iron(III)oxide:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

**Di-n-octyltin-bis-(2-ethylhexylthioglycolate):**

Assessment: Causes damage to organs through prolonged or repeated exposure.

**C.I. Pigment White 6:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

**Polyvinyl chloride:**

Remarks: no data available

**Repeated dose toxicity**

**Components:**

**C.I. Pigment Blue 15:1:**

Species: Rat, male and female
NOAEL: ca. 4500 mg/kg bw/day
Application Route: oral (feed)
Exposure time: 90 d
Number of exposures: daily
Dose: 0, 0.3, 0.6, 1.25, 2.5 and 5 %
Group: yes
Method: OECD Test Guideline 408
GLP: no

**Amorphous silicon dioxide:**

Species: Rat, male and female
NOAEL: 4000 - 4500 mg/kg bw/day
Application Route: oral (feed)
Exposure time: 13 w
Number of exposures: continuously
Dose: 0,5 - 2 - 6,7 % SI in diet
Group: yes
Method: OECD Test Guideline 408
GLP: yes

Species: Rat, male and female
NOAEL: 1,3 mg/m³
LOAEL: 0.0059 mg/l
Application Route: Inhalation
Exposure time: 13 w
Number of exposures: 6 hr/day; 5 days a week
Dose: 1,3 - 5,9 - 31 mg/m3
Group: yes
Method: OECD Test Guideline 413

GLP: yes

Application Route: Skin contact
Remarks: This information is not available.

**Aluminium hydroxide:**

Species: Rat, male and female
NOAEL: 3225 mg/kg bw/day
Application Route: Drinking water
Exposure time: 1 a
Number of exposures: continuously
Dose: 87 - 289 - 867 mg/kg
Group: yes
Method: OECD Test Guideline 426
GLP: yes
Remarks: By analogy with a product of similar composition

Species: Rat, male
NOAEL: 3 mg/m³
LOAEL: 28 mg/m³
Application Route: Inhalation
Test atmosphere: dust/mist
Exposure time: 4 w
Number of exposures: 6 hr/day; 5 days a week
Dose: 0,4 - 3,0 - 28 mg/m3
Group: yes
Method: OECD Test Guideline 412
GLP: no
Remarks: By analogy with a product of similar composition

Application Route: Skin contact
Remarks: The study is not necessary from a scientific perspective.

**Iron(III)oxide:**

Species: Rat, male
Application Route: oral (feed)
Exposure time: 21 d
Number of exposures: daily
Dose: 112,3 - 330,1 mg/100g diet
Group: yes
Method: Repeated Dose Toxicity (subacute study)
GLP: yes
Target Organs: Liver
Remarks: No adverse effect has been observed in chronic toxicity tests.

Species: Rat, male
Application Route: Inhalation
Exposure time: 2 w
Number of exposures: 6 hours/day, 5 days/week
Dose: 185,2- 195,7 - 210,2 mg/m3
Group: yes
Method: OECD Test Guideline 412

GLP: yes
Remarks: No adverse effect has been observed in chronic toxicity tests.

Application Route: Skin contact
Method: Repeated Dose Toxicity (subacute study)
Remarks: The study is not necessary from a scientific perspective.

**Di-n-octyltin-bis-(2-ethylhexylthioglycolate):**

Species: Rat, male and female
NOAEL: 0.5 mg/kg
Application Route: oral (feed)
Exposure time: 90 d
Number of exposures: daily
Dose: 10-25-50-100-250-500-1000 ppm
Group: yes
Method: OECD Test Guideline 408
GLP: no

**C.I. Pigment White 6:**

Species: Rat, male
NOEL: > 24000 mg/kg bw/day
Application Route: oral (gavage)
Exposure time: 29 d
Number of exposures: daily
Dose: 24000 mg/kg
Group: yes
Method: OECD Test Guideline 407
GLP: No information available.

Species: Rat, male and female
NOAEL: 0.01 mg/l
Application Route: Inhalation
Exposure time: 2 a
Number of exposures: 6 hours/day, 5 days/week
Dose: 0,0106 - 0,0507 - 0,250 mg/l
Group: yes
Method: Repeated Dose Toxicity (chronic Toxicity)
GLP: no

**Polyvinyl chloride:**

Remarks: This information is not available.

**Aspiration toxicity**

**Components:**

**C.I. Pigment Blue 15:1:**

No aspiration toxicity classification

**Amorphous silicon dioxide:**
No aspiration toxicity classification

**Aluminium hydroxide:**
No aspiration toxicity classification

**Iron(III)oxide:**
No aspiration toxicity classification

**Di-n-octyltin-bis-(2-ethylhexylthioglycolate):**
No aspiration toxicity classification

**C.I. Pigment White 6:**
No aspiration toxicity classification

**Polyvinyl chloride:**
No aspiration toxicity classification

**Experience with human exposure**

**Product:**

General Information : The possible symptoms known are those derived from the labelling (see section 2).

**Further information**

**Components:**

**C.I. Pigment Blue 15:1:**
Test Type: adsorption
Remarks: Not applicable

**C.I. Pigment White 6:**
Remarks: Lung damage possible.

## SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Product:**

Toxicity to fish :
Remarks: no data available

**Components:**

**C.I. Pigment Blue 15:1:**

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l

End point: mortality
Exposure time: 96 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 203
GLP: no
Remarks: The details of the toxic effect relate to the nominal concentration.

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
End point: Growth rate
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 201
GLP: yes
Remarks: By analogy with a product of similar composition
The details of the toxic effect relate to the nominal concentration.

Toxicity to fish (Chronic toxicity) : Remarks: not required

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): > 1 mg/l
End point: Reproduction rate
Exposure time: 21 d
Test Type: semi-static test
Analytical monitoring: no
Method: OECD Test Guideline 211
GLP: yes
Remarks: The details of the toxic effect relate to the nominal concentration.

Toxicity to microorganisms : EC50 (activated sludge): > 10,000 mg/l
End point: Bacteria toxicity (respiration inhibition)
Exposure time: 3 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 209
GLP: yes
Remarks: The details of the toxic effect relate to the nominal concentration.

Toxicity to soil dwelling organisms : Test Type: artificial soil
LC50 (Eisenia fetida (earthworms)): > 1,000 mg/kg
Exposure time: 14 d
End point: mortality
Method: OECD Test Guideline 207
GLP: yes

Test Type: artificial soil
NOEC (Eisenia fetida (earthworms)): >= 1,000 mg/kg
Exposure time: 14 d
End point: mortality

Method: OECD Test Guideline 207
GLP: yes

Sediment toxicity : NOEC (Lumbriculus variegatus (Worm)): 1000 mg/kg dry weight (d.w.)
Analytical monitoring: no
Sediment: artificial soil
Exposure duration: 28 d
Basis for effect: mortality
Method: OECD 225
GLP: yes

**Amorphous silicon dioxide:**

Toxicity to fish : LL0 (Brachydanio rerio (zebrafish)): 10,000 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 203
GLP: yes
Remarks: The details of the toxic effect relate to the nominal concentration.

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 1,000 mg/l
End point: Immobilization
Exposure time: 24 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 202
GLP: yes
Remarks: The details of the toxic effect relate to the nominal concentration.

Toxicity to algae/aquatic plants : EL50 (Desmodesmus subspicatus (green algae)): > 10,000 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 201
GLP: yes
Remarks: By analogy with a product of similar composition
The details of the toxic effect relate to the nominal concentration.

Toxicity to fish (Chronic toxicity) : NOEC: 86.03 mg/l
Exposure time: 30 d
Method: Other
GLP: no
Remarks: The value is given based on a SAR/AAR approach using OECD Toolbox, DEREK, VEGA QSAR models (CAESAR models), etc.

| | | |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 34.223 mg/l<br>Exposure time: 30 d<br>Method: Other<br>GLP: no<br>Remarks: The value is given based on a SAR/AAR approach using OECD Toolbox, DEREK, VEGA QSAR models (CAESAR models), etc. |
| Sediment toxicity | : | LC50: 148.41 mg/l<br>Duration: 14 d<br>Method: Other<br>GLP: no<br>Remarks: The value is given based on a SAR/AAR approach using OECD Toolbox, DEREK, VEGA QSAR models (CAESAR models), etc. |

**Aluminium hydroxide:**

| | | |
|---|---|---|
| Toxicity to fish | : | NOEC (Salmo trutta (brown trout)): > 0.07 mg/l<br>End point: mortality<br>Exposure time: 96 h<br>Test Type: semi-static test<br>Analytical monitoring: yes<br>Method: OECD Test Guideline 203<br>GLP: yes<br>Remarks: No toxicity at the limit of solubility |
| Toxicity to daphnia and other aquatic invertebrates | : | NOEC (Daphnia magna (Water flea)): > 0.005 mg/l<br>End point: mortality<br>Exposure time: 48 h<br>Test Type: static test<br>Analytical monitoring: yes<br>Method: OECD Test Guideline 202<br>GLP: yes<br>Remarks: No toxicity at the limit of solubility |
| Toxicity to algae/aquatic plants | : | NOEC (Pseudokirchneriella subcapitata (green algae)): >= 0.004 mg/l<br>End point: Growth rate<br>Exposure time: 72 h<br>Test Type: static test<br>Analytical monitoring: yes<br>Method: OECD Test Guideline 201<br>GLP: yes<br>Remarks: No toxicity at the limit of solubility<br><br>EC50 (Lemna minor (duckweed)): 159.7 mg/l<br>End point: Growth rate<br>Exposure time: 72 h<br>Test Type: semi-static test<br>Analytical monitoring: yes<br>Method: OECD Test Guideline 221<br>GLP: yes |

Remarks: By analogy with a product of similar composition

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 56.48 mg/l
End point: mortality
Exposure time: 7 d
Test Type: semi-static test
Analytical monitoring: yes
Method: Other
GLP: yes
Remarks: By analogy with a product of similar composition

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.076 mg/l
End point: Reproduction rate
Exposure time: 21 d
Test Type: semi-static test
Analytical monitoring: yes
Method: OECD Test Guideline 211
GLP: yes
Remarks: By analogy with a product of similar composition
No toxicity at the limit of solubility

**Iron(III)oxide:**

Toxicity to fish : LC50 (Danio rerio (zebra fish)): approx. 100,000 mg/l
Exposure time: 96 h
Test Type: static test
Analytical monitoring: no data available
Method: Umweltbundesamt, 1984
GLP: no
Remarks: The details of the toxic effect relate to the nominal concentration.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 202
GLP: yes
Remarks: The details of the toxic effect relate to the nominal concentration.

Toxicity to algae/aquatic plants : Exposure time:
Remarks: no data available

Toxicity to fish (Chronic toxicity) : Remarks: not reasonable

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: not reasonable

Toxicity to microorganisms : EC50 (activated sludge of a predominantly domestic sewage): > 10,000 mg/l

End point: Bacteria toxicity (respiration inhibition)
Exposure time: 3 h
Test Type: aquatic
Method: ISO 8192
GLP: no

Toxicity to soil dwelling organisms : Remarks: The study is not necessary from a scientific perspective.

Plant toxicity : Remarks: The study is not necessary from a scientific perspective.

Sediment toxicity : Remarks: The study is not necessary from a scientific perspective.

Toxicity to terrestrial organisms : Remarks: The study is not necessary from a scientific perspective.

**Di-n-octyltin-bis-(2-ethylhexylthioglycolate):**

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 24 mg/l
Exposure time: 96 h
Test Type: semi-static test
Analytical monitoring: yes
Method: OECD Test Guideline 203
GLP: yes

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.17 mg/l
Exposure time: 48 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 202
GLP: yes

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): 0.17 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: Directive 87/302/EEC, part C, p. 89
GLP: yes

NOEC (Desmodesmus subspicatus (green algae)): 0.04 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes

M-Factor (Acute aquatic toxicity) : 1

Toxicity to fish (Chronic : Remarks: not required

toxicity)

| | | |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 0.286 mg/l<br>Exposure time: 21 d<br>Test Type: semi-static test<br>Analytical monitoring: yes<br>Method: OECD Test Guideline 211<br>GLP: yes |
| M-Factor (Chronic aquatic toxicity) | : | 1 |
| Toxicity to microorganisms | : | EC50 (activated sludge): > 100 mg/l<br>End point: Bacteria toxicity (respiration inhibition)<br>Exposure time: 3 h<br>Test Type: aquatic<br>Analytical monitoring: no<br>Method: Directive 87/302/EEC, part C, p. 118<br>GLP: yes<br>Remarks: The details of the toxic effect relate to the nominal concentration. |
| Toxicity to soil dwelling organisms | : | Remarks: Not applicable |
| Plant toxicity | : | Remarks: Not applicable |
| Sediment toxicity | : | Remarks: Not applicable |
| Toxicity to terrestrial organisms | : | Remarks: Not applicable |

**C.I. Pigment White 6:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l<br>Exposure time: 96 h<br>Test Type: static test<br>Analytical monitoring: no<br>Method: EPA<br>GLP: yes<br>Remarks: The details of the toxic effect relate to the nominal concentration.<br><br>LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l<br>Exposure time: 96 h<br>Test Type: static test<br>Analytical monitoring: no<br>Method: OECD Test Guideline 203<br>GLP: No information available.<br>Remarks: The details of the toxic effect relate to the nominal concentration.<br><br>LC50 (Cyprinodon variegatus (sheepshead minnow)): > 10,000 mg/l |

Exposure time: 96 h
Test Type: semi-static test
Analytical monitoring: no data available
Method: OECD Test Guideline 203
GLP: yes
Remarks: The details of the toxic effect relate to the nominal concentration.

Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Test Type: static test
Analytical monitoring: no data available
Method: OECD Test Guideline 202
GLP: no data available
Remarks: The details of the toxic effect relate to the nominal concentration.

LC50 (Acartia tonsa): > 10,000 mg/l
Exposure time: 48 h
Analytical monitoring: no data available
Method: ISO 14669 and PARCOM method
GLP: yes
Remarks: The details of the toxic effect relate to the nominal concentration.

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (microalgae)): 61 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: no
Method: EPA
GLP: No information available.
Remarks: The details of the toxic effect relate to the nominal concentration.

EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
End point: Growth rate
Exposure time: 72 h
Analytical monitoring: no data available
Method: ISO 10253
GLP: yes
Remarks: The details of the toxic effect relate to the nominal concentration.

Toxicity to fish (Chronic toxicity) : LC50 (Oncorhynchus mykiss (rainbow trout)): 7.31 mg/l
Exposure time: 28 d
Test Type: static test
Analytical monitoring: yes
Method: Other
GLP: No information available.
Remarks: By analogy with a product of similar composition

Toxicity to microorganisms : EC50 (activated sludge of a predominantly domestic sewage):

> 1,000 mg/l
End point: Bacteria toxicity (respiration inhibition)
Exposure time: 3 h
Test Type: aquatic
Method: OECD Test Guideline 209
GLP: yes
Remarks: The details of the toxic effect relate to the nominal concentration.

NOEC (activated sludge of a predominantly domestic sewage): >= 1,000 mg/l
End point: Bacteria toxicity (respiration inhibition)
Exposure time: 3 h
Test Type: aquatic
Method: OECD Test Guideline 209
GLP: yes
Remarks: The details of the toxic effect relate to the nominal concentration.

Toxicity to soil dwelling organisms : Test Type: artificial soil
NOEC (Folsomia candida): 0,1 ->= 10 %
Exposure time: 28 d
End point: mortality
Method: ISO 11267
GLP: no
Remarks: By analogy with a product of similar composition
This product does not have any known adverse effect on the soil organisms tested.

Plant toxicity : NOEC: >= 10 %
Exposure time: 20 h
End point: Growth
Species: Lactuca sativa (lettuce)
Analytical monitoring: yes
Method: Other
GLP: no
Remarks: By analogy with a product of similar composition
No effect on the growth was observed.

Sediment toxicity : NOEC (Hyalella azteca (Scud)): >= 100000 %
Analytical monitoring: no
Sediment: artificial soil
Exposure duration: 28 d
Nominal / Measured: nominal
Basis for effect: mortality
Method: Other
GLP: no
Remarks: By analogy with a product of similar composition

NOEC: >= 14989 mg/kg dry weight (d.w.)
Analytical monitoring: no data available
Sediment: Natural sediment
Exposure duration: 10 d

Nominal / Measured: nominal
Basis for effect: mortality
Method: Other
GLP: yes

**Polyvinyl chloride:**

| | | |
|---|---|---|
| Toxicity to fish | : | no toxicity, except ingestion<br>Remarks: Not applicable |
| Toxicity to daphnia and other aquatic invertebrates | : | Remarks: Not applicable |
| Toxicity to algae/aquatic plants | : | Remarks: Not applicable |
| Toxicity to fish (Chronic toxicity) | : | no toxicity, except ingestion<br>Remarks: Not applicable |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | Remarks: Not applicable |
| Toxicity to microorganisms | : | Remarks: Not applicable |
| Toxicity to soil dwelling organisms | : | Remarks: Not applicable |
| Plant toxicity | : | Remarks: Not applicable |
| Sediment toxicity | : | Remarks: Not applicable |
| Toxicity to terrestrial organisms | : | no toxicity, except ingestion<br>Remarks: Not applicable |

**Persistence and degradability**

**Components:**

**C.I. Pigment Blue 15:1:**

| | | |
|---|---|---|
| Biodegradability | : | aerobic<br>Inoculum: activated sludge<br>Concentration: 107 mg/l<br>Biochemical Oxygen Demand (BOD)<br>Result: Not biodegradable<br>Biodegradation: < 1 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301F<br>GLP: no |
| Physico-chemical removability | : | Remarks: Not readily biodegradable. |
| Stability in water | : | Remarks: Not applicable |

| | | |
|---|---|---|
| Photodegradation | : | Test Type: air<br>Sensitiser: OH<br>Concentration: 50,000 1/cm3<br>Rate constant: 8.525E-11 cm3/s<br>Method: other (calculated)<br>GLP: no |

**Amorphous silicon dioxide:**

| | | |
|---|---|---|
| Biodegradability | : | Remarks: Not applicable |

**Aluminium hydroxide:**

| | | |
|---|---|---|
| Biodegradability | : | Remarks: Not applicable |

**Iron(III)oxide:**

| | | |
|---|---|---|
| Biodegradability | : | Remarks: Not applicable for inorganic compound. |
| Physico-chemical removability | : | Remarks: Not applicable |

**Di-n-octyltin-bis-(2-ethylhexylthioglycolate):**

| | | |
|---|---|---|
| Biodegradability | : | aerobic<br>Inoculum: activated sludge<br>Concentration: 50 mg/l<br>Biochemical Oxygen Demand (BOD)<br>Result: Not readily biodegradable.<br>Biodegradation: 30 - 40 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301F<br>GLP: yes |

**C.I. Pigment White 6:**

| | | |
|---|---|---|
| Biodegradability | : | Remarks: Not applicable for inorganic compound. |

**Polyvinyl chloride:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Remarks: The polymer is too large to be bioavailable.<br>Not applicable due to insolubility in water. This product does not come into contact with the effluent when it is used for its purpose, otherwise it can be removed by filtration operations. |

**Bioaccumulative potential**

**Product:**

| | | |
|---|---|---|
| Bioaccumulation | : | Remarks: not tested. |

**Components:**

**C.I. Pigment Blue 15:1:**

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

Partition coefficient: n-octanol/water : Remarks: Not applicable

**Iron(III)oxide:**

Bioaccumulation : Remarks: Does not accumulate in organisms.

**Di-n-octyltin-bis-(2-ethylhexylthioglycolate):**

Bioaccumulation : Species: Oncorhynchus mykiss (rainbow trout)
Bioconcentration factor (BCF): 99 - 1,294
Exposure time: 30 d
Concentration: DOT: 0,25 - 2,5 µg/l
Method: OECD Guide-line 305 B
GLP: yes

**C.I. Pigment White 6:**

Bioaccumulation : Species: Oncorhynchus mykiss (rainbow trout)
Bioconcentration factor (BCF): 20 - 200
Exposure time: 14 d
Concentration: 0.1 - 1 mg/l
Method: Other
GLP: No information available.
Remarks: Does not accumulate in organisms.

Partition coefficient: n-octanol/water : Remarks: inorganic

**Polyvinyl chloride:**

Bioaccumulation : Remarks: Not applicable

**Mobility in soil**

**Product:**

Distribution among environmental compartments : Remarks: not tested.

**Components:**

**C.I. Pigment Blue 15:1:**

Distribution among environmental compartments : adsorption
Medium: Soil
Remarks: Not expected to adsorb on soil.

**Iron(III)oxide:**

Mobility : Remarks: Known distribution to environmental compartments

| | | |
|---|---|---|
| Distribution among environmental compartments | : | Remarks: Not applicable |

**Di-n-octyltin-bis-(2-ethylhexylthioglycolate):**

| | | |
|---|---|---|
| Distribution among environmental compartments | : | Remarks: Not applicable |

**C.I. Pigment White 6:**

| | | |
|---|---|---|
| Mobility | : | Remarks: Adsorption to solid soil phase is possible. |
| Distribution among environmental compartments | : | Adsorption/Soil<br>Medium: water - soil<br>log Koc: 4.61<br>Method: Other |

**Polyvinyl chloride:**

| | | |
|---|---|---|
| Distribution among environmental compartments | : | Remarks: The product is insoluble and sinks in water. |

**Other adverse effects**

**Product:**

| | | |
|---|---|---|
| Results of PBT and vPvB assessment | : | Remarks: No information is available as no chemical safety report (CSR) is required. |
| Additional ecological information | : | Do not allow to enter ground water, waterways or waste water. |

**Components:**

**C.I. Pigment Blue 15:1:**

| | | |
|---|---|---|
| Environmental fate and pathways | : | not available |
| Results of PBT and vPvB assessment | : | The substance is not identified as a PBT or as a vPvB substance. |
| Additional ecological information | : | The product should not be allowed to enter drains, water courses or the soil. |

**Amorphous silicon dioxide:**

| | | |
|---|---|---|
| Environmental fate and pathways | : | not available |
| Results of PBT and vPvB assessment | : | The substance is not identified as a PBT or as a vPvB substance. |
| Additional ecological information | : | Do not allow to enter ground water, waterways or waste water. |

**Aluminium hydroxide:**

| | | |
|---|---|---|
| Environmental fate and pathways | : | not available |
| Results of PBT and vPvB assessment | : | Remarks: Not applicable |
| Additional ecological information | : | Do not allow to enter ground water, waterways or waste water. |

**Iron(III)oxide:**

| | | |
|---|---|---|
| Environmental fate and pathways | : | not available |
| Results of PBT and vPvB assessment | : | The substance is not identified as a PBT or as a vPvB substance. |
| Additional ecological information | : | Do not allow to enter ground water, waterways or waste water. |

**Di-n-octyltin-bis-(2-ethylhexylthioglycolate):**

| | | |
|---|---|---|
| Environmental fate and pathways | : | not available |
| Results of PBT and vPvB assessment | : | This substance is not considered to be persistent, bioaccumulating and toxic (PBT). |
| Additional ecological information | : | Do not allow to enter ground water, waterways or waste water. |

**C.I. Pigment White 6:**

| | | |
|---|---|---|
| Environmental fate and pathways | : | not available |
| Results of PBT and vPvB assessment | : | This substance is not considered to be persistent, bioaccumulating and toxic (PBT). |
| Additional ecological information | : | Do not allow to enter ground water, waterways or waste water. |

**Polyvinyl chloride:**

| | | |
|---|---|---|
| Environmental fate and pathways | : | no data available |
| Results of PBT and vPvB assessment | : | Remarks: Not applicable |
| Additional ecological information | : | Has not been tested due to insolubility in water. |

## SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

Waste from residues : Dispose of this product in accordance with all applicable local, state and federal regulations.

Contaminated packaging : Regulations concerning reuse or disposal of used packaging materials must be observed.

## SECTION 14. TRANSPORT INFORMATION

## SECTION 15. REGULATORY INFORMATION

**NPRI Components** : Copper, [29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32]-, (1,3-dihydro-1,3-dioxo-2H-isoindol-2-yl)methyl derivs.
C.I. Pigment Blue 15:1

**The components of this product are reported in the following inventories:**

DSL : All components of this product are on the Canadian DSL

**Canadian lists**

No substances are subject to a Significant New Activity Notification.

## SECTION 16. OTHER INFORMATION

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL : Canada. British Columbia OEL
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA : 8-hour, time-weighted average
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average
CA BC OEL / STEL : short-term exposure limit
CA QC OEL / TWAEV : Time-weighted average exposure value
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-3 / TWA : 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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