

RENOL-SFR CHAMPAGNE-PN

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SECTION 1. IDENTIFICATION

Identification of the company:

Clariant Plastics & Coating USA LLC
4000 Monroe Road
Charlotte, NC, 28205
Telephone No.: +1 704 331 7000

Information of the substance/preparation:

BU Masterbatches
Product Stewardship, +1-704-331-7710
e-mail: SDS.NORAM@clariant.com

Emergency tel. number: 800-424-9300 (CHEMTREC)**Trade name:****RENOL-SFR CHAMPAGNE-PN****Material number:**

EV82800002

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

Skin sensitisation : Category 1

Reproductive toxicity : Category 1B

Specific target organ toxicity : Category 1
- repeated exposure (Oral)Specific target organ toxicity : Category 2 (Lungs)
- repeated exposure**GHS label elements**

Hazard pictograms :



Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.
H360 May damage fertility or the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure if swallowed.
H373 May cause damage to organs () through prolonged or

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repeated exposure.

Precautionary statements

:

Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P272 Contaminated work clothing must not be allowed out of the workplace.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

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 Yellow 164 | 68412-38-4 | 0.1 - 1 |
| Aluminium oxide | 1344-28-1 | 0.1 - 1 |
| Calcium distearate | 1592-23-0 | 0.1 - 1 |
| Reaction mass of fatty acids, montan wax and fatty acids, montan wax, ethylene acids and montan wax | Not Assigned | 1 - 5 |
| C.I. Pigment Brown 24 | 68186-90-3 | 1 - 5 |
| Di-n-octyltin-bis-(2-ethylhexylthioglycolate) | 15571-58-1 | 1 - 5 |
| C.I. Pigment White 6 | 13463-67-7 | 10 - 30 |
| Mica-Group minerals | 12001-26-2 | 10 - 30 |
| Polyvinyl chloride | 9002-86-2 | 30 - 60 |

Any concentration shown as a range is due to batch variation.

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SECTION 4. FIRST AID MEASURES

- General advice : Ensure that the First Aid Personnel are aware of the product involved, and take precautions to protect themselves (e.g. wear personal protection equipment).
Get medical advice/ attention if you feel unwell.
- 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.
Wash off with soap and water.
Get medical attention if irritation develops and persists.
- 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:
Hydrogen chloride
Carbon monoxide
Carbon dioxide (CO₂)
Sulphur oxides
Metal oxides

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Further information : Combustible material
In the event of fire and/or explosion do not breathe fumes.
During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion
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.
Do not allow run-off from fire fighting to enter drains or water courses.
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.
Avoid contact with skin, eyes and clothing.
Wash thoroughly after handling.

Environmental precautions : Do not allow contact with soil, surface or ground water.
Prevent product from entering drains.

Methods and materials for containment and cleaning up : Non-sparking tools should be used.
Avoid dust formation.
Take measures to prevent the build up of electrostatic charge.
Sweep up and shovel into suitable containers for disposal.
Clean contaminated surface thoroughly.

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.
Avoid dust formation.
Take measures to prevent the build up of electrostatic charge.
Ensure all equipment is electrically grounded before beginning transfer operations.
Use only non-sparking tools.

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

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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 Brown 24 | 68186-90-3 | TWA | 0.5 mg/m ³ (antimony) | CA AB OEL |
| | | TWAEV | 0.5 mg/m ³ (antimony) | CA QC OEL |
| | | TWA | 0.5 mg/m ³ (antimony) | CA BC OEL |
| | | TWA | 0.5 mg/m ³ (antimony) | ACGIH |
| C.I. Pigment Yellow 164 | 68412-38-4 | TWA | 0.5 mg/m ³ (antimony) | CA AB OEL |
| | | TWA | 0.2 mg/m ³ (Manganese) | CA AB OEL |
| | | TWAEV | 0.5 mg/m ³ (antimony) | CA QC OEL |
| | | TWAEV (total dust) | 0.2 mg/m ³ (Manganese) | CA QC OEL |
| | | TWA | 0.5 mg/m ³ (antimony) | CA BC OEL |
| | | TWA (Respirable) | 0.02 mg/m ³ (Manganese) | CA BC OEL |
| | | TWA (Total) | 0.2 mg/m ³ (Manganese) | CA BC OEL |
| | | TWA | 0.5 mg/m ³ (antimony) | ACGIH |
| | | TWA (Inhalable fraction) | 0.1 mg/m ³ (Manganese) | ACGIH |
| | | TWA (Respirable fraction) | 0.02 mg/m ³ (Manganese) | ACGIH |
| C.I. Pigment White 6 | 13463-67-7 | TWA | 10 mg/m ³ | CA AB OEL |
| | | TWA (Total dust) | 10 mg/m ³ | CA BC OEL |

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| | | | | |
|---------------------|------------|--------------------------------------|-------------------------|-----------|
| | | TWA (respirable dust fraction) | 3 mg/m3 | CA BC OEL |
| | | TWAEV (total dust) | 10 mg/m3 | CA QC OEL |
| Aluminium oxide | 1344-28-1 | TWA | 10 mg/m3 | CA AB OEL |
| | | TWAEV (total dust) | 10 mg/m3 (Aluminium) | CA QC OEL |
| | | TWA (Respirable) | 1 mg/m3 (Aluminium) | CA BC OEL |
| | | TWA (Respirable fraction) | 1 mg/m3 (Aluminium) | ACGIH |
| Calcium distearate | 1592-23-0 | TWA | 10 mg/m3 | CA AB OEL |
| | | TWA | 10 mg/m3 | CA BC OEL |
| | | TWA (Inhalable fraction) | 10 mg/m3 | ACGIH |
| | | TWA (Respirable fraction) | 3 mg/m3 | ACGIH |
| 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 |
| Mica-Group minerals | 12001-26-2 | TWA (Respirable) | 3 mg/m3 | CA AB OEL |
| | | TWA (Respirable) | 3 mg/m3 | CA BC OEL |
| | | TWAEV (respirable dust) | 3 mg/m3 | CA QC OEL |
| | | TWA (Respirable fraction) | 3 mg/m3 | ACGIH |

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 : If dusty conditions exist, use NIOSH approved respirator with high efficiency (p-100) filter media.

Hand protection

Remarks : Nitrile rubber gloves. Impervious butyl rubber gloves PVC

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Neoprene gloves

- Eye protection : Safety glasses with side-shields
- Skin and body protection : Wear protective clothing, including long sleeves and gloves, to prevent skin contact.
- 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 : powder
- Colour : brown
- 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 : not determined

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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
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.
Heating can release hazardous gases.
Keep away from heat, sparks, open flames, and other sources of ignition.
If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
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.
Keep away from heat.
Keep away from flames and sparks.

Incompatible materials : Strong oxidizing agents
none
Strong acids and oxidizing agents

Hazardous decomposition products : When handled and stored appropriately, no dangerous decomposition products are known
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

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higher than 300 J/g.

SECTION 11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure**

Inhalation

Eye contact

Skin contact

Acute toxicity**Product:**

Acute inhalation toxicity : Acute toxicity estimate: 87.5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:**Aluminium oxide:**

Acute oral toxicity : LD50 (Rat, male and female): > 10,000 mg/kg
Method: OECD Test Guideline 401
GLP: No information available.

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 or mixture has no acute inhalation toxicity

Acute dermal toxicity : Remarks: Not applicable

Calcium distearate:

Acute oral toxicity : LD50 (Rat, female): > 2,000 mg/kg
Method: OECD Test Guideline 423
GLP: yes

Acute inhalation toxicity : LC50 (Rat): > 3 mg/l
Exposure time: 4 h
Method: OECD Test Guideline 403
GLP: yes
Remarks: By analogy with a product of similar composition

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

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Remarks: By analogy with a product of similar composition

Reaction mass of fatty acids, montan wax and fatty acids, montan wax, ethylene acids and montan wax:

- Acute oral toxicity : LD50 (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 401
GLP: yes
- Acute inhalation toxicity : Remarks: not required
- Acute dermal toxicity : LD50 (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 402
GLP: yes

C.I. Pigment Brown 24:

- Acute oral toxicity : LD50 (Rat, male and female): > 10,000 mg/kg
Method: BASF test
GLP: no
- Acute inhalation toxicity : Remarks: Not applicable
- Acute dermal toxicity : Remarks: Not applicable

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

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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:**Aluminium oxide:**

Species: Rabbit

Exposure time: 24 h

Method: OECD Test Guideline 404

Result: No skin irritation

GLP: No information available.

Calcium distearate:

Species: Rabbit

Exposure time: 4 h

Method: OECD Test Guideline 404

Result: No skin irritation

GLP: yes

Remarks: By analogy with a product of similar composition

Reaction mass of fatty acids, montan wax and fatty acids, montan wax, ethylene acids and montan wax:

Species: Rabbit

Exposure time: 4 h

Method: OECD Test Guideline 404

Result: No skin irritation

GLP: yes

C.I. Pigment Brown 24:

Species: Rabbit

Exposure time: 24 h

Method: Draize Test

Result: No skin irritation

GLP: no

C.I. Pigment White 6:

Species: Rabbit

Exposure time: 4 h

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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:**Aluminium oxide:**

Result: Mild eye irritation

Calcium distearate:

Species: rabbit eye
Result: No eye irritation
Method: OECD Test Guideline 405
GLP: yes
Remarks: By analogy with a product of similar composition

Reaction mass of fatty acids, montan wax and fatty acids, montan wax, ethylene acids and montan wax:

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

C.I. Pigment Brown 24:

Species: rabbit eye
Result: slight irritation
Method: FDA guideline
GLP: no

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

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Method: OECD Test Guideline 405
GLP: No information available.

Polyvinyl chloride:

Remarks: This information is not available.

Respiratory or skin sensitisation**Product:**

Result: Causes sensitisation.

Components:**Aluminium oxide:**

Test Type: Draize Test
Exposure routes: Dermal
Species: Guinea pig
Method: Draize Test
Result: Not a skin sensitizer.
GLP: no

Test Type: Respiratory system
Exposure routes: inhalation (dust/mist/fume)
Species: Mouse
Method: Other
Result: Not a skin sensitizer.
GLP: no

Calcium distearate:

Test Type: Local lymph node assay (LLNA)
Exposure routes: Dermal
Species: Mouse
Method: OECD Test Guideline 429
Result: Not a skin sensitizer.
GLP: yes
Remarks: By analogy with a product of similar composition

Test Type: Respiratory system
Exposure routes: Inhalation
Remarks: This information is not available.

Reaction mass of fatty acids, montan wax and fatty acids, montan wax, ethylene acids and montan wax:

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

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C.I. Pigment Brown 24:

Remarks: Not applicable

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:****Aluminium oxide:**

Genotoxicity in vitro

: Test Type: In vitro gene mutation study in mammalian cells
Test system: mouse lymphoma cells
Concentration: 6,1 - 780 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

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- Genotoxicity in vivo : Test Type: Chromosome Aberration Test
Species: Rat (female)
Strain: wistar
Cell type: Bone marrow
Application Route: oral (gavage)
Exposure time: Single exposure
Dose: 500 - 1000 - 2000 mg/kg
Method: OECD Test Guideline 475
Result: positive
GLP: No information available.
- Test Type: Micronucleus test
Species: Rat (female)
Strain: wistar
Cell type: Bone marrow
Application Route: oral (gavage)
Exposure time: Single exposure
Dose: 500 - 1000 - 2000 mg/kg
Method: OECD Test Guideline 474
Result: positive
GLP: No information available.
- Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.
- Calcium distearate:**
- Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Method: OECD Test Guideline 471
Result: negative
GLP: yes
- Test Type: In vitro gene mutation study in mammalian cells
Test system: mouse lymphoma cells
Method: OECD Test Guideline 476
Result: negative
GLP: yes
Remarks: By analogy with a product of similar composition
- Test Type: Cytogenetic assay
Test system: V79 cells (embryonic lung fibroblasts) of the Chinese hamster
Method: OECD Test Guideline 473
Result: negative
GLP: yes
Remarks: By analogy with a product of similar composition
- Germ cell mutagenicity - Assessment : It is concluded that the product is not mutagenic based on evaluation of several mutagenicity tests.

Reaction mass of fatty acids, montan wax and fatty acids, montan wax, ethylene acids and montan wax:

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Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Concentration: 4 - 10000 µg/plate
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster lung cells
Concentration: 0,3 - 35 µg/ml
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: negative
GLP: yes

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster lung cells
Concentration: 4,4 - 560 µf/ml
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: yes

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

C.I. Pigment Brown 24:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Concentration: 100 - 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: 2,5 - 5000 µg/plate
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster lung cells
Concentration: 0,5 - 900 µg/ml
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 487
Result: negative
GLP: yes

Test Type: In vitro gene mutation study in mammalian cells

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Test system: mouse lymphoma cells
Concentration: 3,13 - 100 µg/ml
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: yes

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.

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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:****Aluminium oxide:**

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

Calcium distearate:

Carcinogenicity - Assessment : Not classifiable as a human carcinogen.

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Reaction mass of fatty acids, montan wax and fatty acids, montan wax, ethylene acids and montan wax:

Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

C.I. Pigment Brown 24:

Carcinogenicity - Assessment : Not classifiable as a human carcinogen.

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:****Aluminium oxide:**

Effects on fertility : Species: Rat, male and female
Strain: Sprague-Dawley
Application Route: Drinking water
Dose: 57 - 189 - 567 mg/kg
General Toxicity - Parent: NOAEL: ca. 567 mg/kg body weight
General Toxicity F1: NOAEL: ca. 57 mg/kg body weight
Method: Other
GLP: yes
Remarks: By analogy with a product of similar composition

Effects on foetal development : Species: Rat
Strain: wistar
Application Route: oral (gavage)
Dose: 126 - 251 - 503 mg/kg
Frequency of Treatment: 2 daily
General Toxicity Maternal: NOAEL: > 100 mg/kg body weight
Teratogenicity: NOAEL: 503 mg/kg body weight
Method: OECD Test Guideline 414
GLP: No information available.
Remarks: By analogy with a product of similar composition

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.

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Calcium distearate:

Effects on fertility : Species: Rat
Application Route: Oral
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 : Species: Rat
Application Route: Oral
Teratogenicity: NOAEL: > 1,000 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes
Remarks: By analogy with a product of similar composition

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

Reaction mass of fatty acids, montan wax and fatty acids, montan wax, ethylene acids and montan wax:

Effects on fertility : Test Type: One generation study
Species: Rat, male and female
Strain: Sprague-Dawley
Application Route: oral (gavage)
Dose: 10 - 100 - 1000 mg/kg
Duration of Single Treatment: > 52 d
Frequency of Treatment: 1 daily
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: Pre-natal
Species: Rat, female
Strain: Sprague-Dawley
Application Route: oral (gavage)
Dose: 50 - 250 - 1000 mg/kg
Duration of Single Treatment: 13 d
Frequency of Treatment: 1 daily
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 414
GLP: yes

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

C.I. Pigment Brown 24:

Effects on fertility : Test Type: One generation study

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Species: Rat, male and female
Strain: Sprague-Dawley
Application Route: oral (gavage)
Dose: 250 - 500 - 1000 mg/kg
General Toxicity - Parent: NOAEL: \geq 1,000 mg/kg body weight
General Toxicity F1: NOAEL: \geq 1,000 mg/kg body weight
Method: OECD Test Guideline 422
GLP: yes

Effects on foetal
development

: Species: Rat
Strain: Sprague-Dawley
Application Route: oral (gavage)
Dose: 250 - 500 - 1000 mg/kg
General Toxicity Maternal: NOAEL: \geq 1,000 mg/kg body weight
Teratogenicity: NOAEL: \geq 1,000 mg/kg body weight
Method: OECD Test Guideline 422
GLP: yes

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
Species: Rat, male and female
Strain: Sprague-Dawley
Application Route: oral (feed)
Dose: 20 - 60 -200 ppm
General Toxicity - Parent: NOAEL: ca. 1.6 mg/kg body weight
General Toxicity F1: NOAEL: 1.6 mg/kg body weight
Method: OECD Test Guideline 416
GLP: yes
Remarks: By analogy with a product of similar composition

Effects on foetal
development

: Species: Rabbit
Strain: New Zealand white
Application Route: oral (gavage)
Dose: 4 - 20 - 80 mg/kg
General Toxicity Maternal: NOAEL: 20 mg/kg body weight
Teratogenicity: NOAEL: 80 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes

Reproductive toxicity -
Assessment

: Clear evidence of adverse effects on development, based on animal experiments.
Classification as "teratogenic" is not justifiable.

C.I. Pigment White 6:

Effects on fertility

: Remarks: no data available

Effects on foetal

: Test Type: Pre-natal

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development

Species: Rat, female
Strain: wistar
Application Route: oral (gavage)
Dose: 100, 300, 1000 mg/kg bw
Duration of Single Treatment: 14 d
Frequency of Treatment: 1 daily
General Toxicity Maternal: NOAEL: 1,000 mg/kg body weight
Developmental Toxicity: NOAEL: 1,000 mg/kg body weight
Embryo-foetal toxicity: NOEL: 1,000 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes
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.
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 - Assessment : No information available.
No information available.

STOT - single exposure**Components:****Aluminium oxide:**

Target Organs: Lungs

Assessment: The substance or mixture is classified as specific target organ toxicant, single exposure, category 3 with respiratory tract irritation.

Calcium distearate:

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

Reaction mass of fatty acids, montan wax and fatty acids, montan wax, ethylene acids and montan wax:

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

C.I. Pigment Brown 24:

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

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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:****Aluminium oxide:**

Target Organs: Lungs

Assessment: The substance or mixture is classified as specific target organ toxicant, repeated exposure, category 2.

Calcium distearate:

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

Reaction mass of fatty acids, montan wax and fatty acids, montan wax, ethylene acids and montan wax:

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

C.I. Pigment Brown 24:

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:****Aluminium oxide:**

Species: Rat, male and female

NOAEL: 57 mg/kg

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Application Route: Drinking water
Exposure time: 1 a
Number of exposures: continuously
Dose: 57 - 189 - 567 mg/kg
Group: yes
Method: OECD Test Guideline 426
GLP: yes
Remarks: By analogy with a product of similar composition

Species: Rat
LOAEL: 0.070 mg/l
Application Route: Inhalation
Exposure time: 6 m
Number of exposures: 6 hr/day; 5 days a week
Dose: 15-30-50-70-100 mg Al/m³
Method: OECD Test Guideline 413
GLP: No information available.

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

Calcium distearate:

Species: Rat
NOAEL: > 2,000 mg/kg
Application Route: Oral
Method: OECD Test Guideline 407
GLP: yes

Reaction mass of fatty acids, montan wax and fatty acids, montan wax, ethylene acids and montan wax:

Species: Rat, male and female
NOAEL: 1000 mg/kg bw/day
Application Route: oral (gavage)
Exposure time: > 70 d
Number of exposures: once daily
Dose: 10 - 100 -1000 mg/kg
Group: yes
Method: OECD Test Guideline 422
GLP: yes

C.I. Pigment Brown 24:

Species: Rat, male and female
NOAEL: 500 mg/kg
Application Route: oral (feed)
Exposure time: 90 d
Number of exposures: daily
Dose: 0,5 - 5 - 50 - 500 mg/kg
Group: yes
Method: OECD Test Guideline 408
GLP: No information available.

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Application Route: Inhalation
Remarks: not tested.

Application Route: Skin contact
Remarks: not tested.

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:****Aluminium oxide:**

No aspiration toxicity classification

Calcium distearate:

No aspiration toxicity classification

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Reaction mass of fatty acids, montan wax and fatty acids, montan wax, ethylene acids and montan wax:

No aspiration toxicity classification

C.I. Pigment Brown 24:

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 White 6:

Remarks: Lung damage possible.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Toxicity to fish :
Remarks: no data available

Components:

Aluminium oxide:

Toxicity to fish : NOEC (Salmo trutta (brown trout)): > 0.072 mg/l
Exposure time: 96 h
Test Type: semi-static test
Analytical monitoring: yes
Method: OECD Test Guideline 203
GLP: yes

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| | |
|--|---|
| Toxicity to daphnia and other aquatic invertebrates | : NOEC (Daphnia magna (Water flea)): > 0.071 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 | : NOEC (Pseudokirchneriella subcapitata (green algae)): >= 0.052 mg/l End point: Growth rate Exposure time: 72 h Test Type: static test Analytical monitoring: yes Method: OECD Test Guideline 201 GLP: yes EC50 (Pseudokirchneriella subcapitata (green algae)): 1.05 mg/l End point: Growth rate Exposure time: 72 h Test Type: static test Analytical monitoring: yes Method: OECD Test Guideline 201 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 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 |
| 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 | : Remarks: Not applicable |

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organisms

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Calcium distearate:

Toxicity to fish : LC50 (*Oryzias latipes*): > 100 mg/l
Exposure time: 96 h
Test Type: static test
Method: OECD Test Guideline 203
GLP: yes

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): > 100 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202
GLP: yes

Toxicity to algae/aquatic plants : EC50 (*Pseudokirchneriella subcapitata* (green algae)): > 100 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201
GLP: yes

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (*Daphnia magna* (Water flea)): > 0.22 mg/l
Exposure time: 21 d
Test Type: semi-static test
Method: OECD Test Guideline 211
GLP: yes
Remarks: By analogy with a product of similar composition

Toxicity to microorganisms : EC50 (activated sludge): > 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: By analogy with a product of similar composition

Toxicity to soil dwelling organisms : Remarks: Not applicable

Plant toxicity : Remarks: Not applicable

Sediment toxicity : Remarks: no data available

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Toxicity to terrestrial organisms : Remarks: Not applicable

Reaction mass of fatty acids, montan wax and fatty acids, montan wax, ethylene acids and montan wax:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10 g/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 : EC50 (Daphnia magna (Water flea)): > 10 g/l
End point: Immobilization
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 : ErC50 (Desmodesmus subspicatus (green algae)): > 320 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes
Remarks: The details of the toxic effect relate to the nominal concentration.

ErC10 (Desmodesmus subspicatus (green algae)): > 320 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes
Remarks: 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) : NOELR (Daphnia magna (Water flea)): 100 mg/l
End point: Reproduction rate
Exposure time: 21 d
Test Type: semi-static test
Analytical monitoring: no

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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 g/l
End point: Bacteria toxicity (respiration inhibition)
Exposure time: 3 h
Test Type: Respiration inhibition
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
NOEC (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

C.I. Pigment Brown 24:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l
Exposure time: 96 h
Test Type: static test
Analytical monitoring: no
Method: DIN 38412 T.15
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 : EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: no

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Method: OECD Test Guideline 201

GLP: yes

Remarks: 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) : Remarks: not required

Toxicity to microorganisms : EC50 (*Pseudomonas putida*): > 10,000 mg/l
End point: Bacteria toxicity (respiration inhibition)
Exposure time: 0.5 h
Test Type: aquatic
Analytical monitoring: no
Method: DIN 38412 T.27
GLP: no
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

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

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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 toxicity) : Remarks: not required

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.286 mg/l
Exposure time: 21 d
Test Type: semi-static test
Analytical monitoring: yes
Method: OECD Test Guideline 211
GLP: yes

M-Factor (Chronic aquatic toxicity) : 1

Toxicity to microorganisms : EC50 (activated sludge): > 100 mg/l
End point: Bacteria toxicity (respiration inhibition)
Exposure time: 3 h
Test Type: aquatic
Analytical monitoring: no
Method: Directive 87/302/EEC, part C, p. 118
GLP: yes
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
Exposure time: 96 h
Test Type: static test
Analytical monitoring: no
Method: EPA
GLP: yes

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Remarks: The details of the toxic effect relate to the nominal concentration.

LC50 (*Oncorhynchus mykiss* (rainbow trout)): > 100 mg/l

Exposure time: 96 h

Test Type: static test

Analytical monitoring: no

Method: OECD Test Guideline 203

GLP: No information available.

Remarks: The details of the toxic effect relate to the nominal concentration.

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

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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): $\geq 1,000$ 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 $\rightarrow \geq 10$ %
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.

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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
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
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
Remarks: Not applicable

Persistence and degradability**Components:****Aluminium oxide:**

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Biodegradability : Remarks: Not applicable

Calcium distearate:Biodegradability : Result: Readily biodegradable.
Biodegradation: 93 %
Method: OECD Test Guideline 301CResult: Readily biodegradable.
Biodegradation: 99 %
Method: OECD Test Guideline 301B**Reaction mass of fatty acids, montan wax and fatty acids, montan wax, ethylene acids and montan wax:**Biodegradability : aerobic
Inoculum: activated sludge
Concentration: 4 mg/l
Biochemical Oxygen Demand (BOD)
Result: Not readily biodegradable.
Biodegradation: 54 %
Exposure time: 28 d
Method: OECD Test Guideline 301D
GLP: yes

Stability in water : Remarks: Not applicable

C.I. Pigment Brown 24:

Biodegradability : Remarks: Not applicable for inorganic compound.

Physico-chemical removability : Remarks: Inorganic product, cannot be eliminated from the water by biological purification processes.

Di-n-octyltin-bis-(2-ethylhexylthioglycolate):Biodegradability : aerobic
Inoculum: activated sludge
Concentration: 50 mg/l
Biochemical Oxygen Demand (BOD)
Result: Not readily biodegradable.
Biodegradation: 30 - 40 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
GLP: yes**C.I. Pigment White 6:**

Biodegradability : Remarks: Not applicable for inorganic compound.

Polyvinyl chloride:Biodegradability : Result: Not readily biodegradable.
Remarks: The polymer is too large to be bioavailable.

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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:**Aluminium oxide:**

Bioaccumulation : Remarks: Not applicable

Calcium distearate:

Bioaccumulation : Remarks: Due to the low logPow bioaccumulation is not expected

Reaction mass of fatty acids, montan wax and fatty acids, montan wax, ethylene acids and montan wax:

Partition coefficient: n-octanol/water : log Pow: 0.9 (20 °C)
pH: 7
Method: other (calculated)

C.I. Pigment Brown 24:

Bioaccumulation : Remarks: Not relevant for inorganic substances

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

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Polyvinyl chloride:

Bioaccumulation : Remarks: Not applicable

Mobility in soil**Product:**

Distribution among environmental compartments : Remarks: not tested.

Components:**Aluminium oxide:**

Distribution among environmental compartments : Remarks: Not applicable

C.I. Pigment Brown 24:

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
Medium: water - soil
log Koc: 4.61
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:**Aluminium oxide:**

Environmental fate and pathways : not available

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Results of PBT and vPvB assessment : Remarks: Not applicable

Additional ecological information : Do not allow to enter ground water, waterways or waste water.

Calcium distearate:

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.

Reaction mass of fatty acids, montan wax and fatty acids, montan wax, ethylene acids and montan wax:

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.

C.I. Pigment Brown 24:

Environmental fate and pathways : not available

Results of PBT and vPvB assessment : The substance is inorganic, thus a PBT and vPvB criteria assessment is not applicable according to Annex XIII of Regulation (EC) 1907/2006.

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

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pathways

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

TDG not restricted

IATA not restricted

IMDG not restricted

SECTION 15. REGULATORY INFORMATION

NPRI Components : Chromium (III) compound
Antimony compounds
Manganese Compound

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.

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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 |
| 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 QC OEL / TWA | : | Time-weighted average exposure value |

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; CPR - Controlled Products Regulations; 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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