Substance key: 000000792085	Revision Date: 04/29/2019
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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-WHITE SB02800037-ZN**
Material number: SB02800037

Chemical family: Colourant preparation
Carrier: ABS

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: ABS

Components

Chemical name	CAS-No.	Concentration (% w/w)
N,N'-Ethylenedi(stearamide)	110-30-5	1 - 5
Amorphous silicon dioxide	7631-86-9	1 - 5
Aluminium hydroxide	21645-51-2	1 - 5
C.I. Pigment White 6	13463-67-7	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: Styrene Hydrogen cyanide (hydrocyanic acid)

Acrylonitrile
Carbon monoxide
Carbon dioxide (CO2)
Take measures to prevent the build up of electrostatic charge.
Dust can form an explosive mixture in air.
Sulphur oxides
Hydrogen sulfide (H2S)

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 : Avoid dust formation.
Take measures to prevent the build up of electrostatic charge.
Sweep up and shovel into suitable containers for disposal.
Take up uncontaminated material and pass on for further processing.
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
N,N'-Ethylenedi(stearamide)	110-30-5	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
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
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	1 mg/m3	ACGIH

		(Respirable fraction)	(Aluminium)	

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.
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	:	white
Odour	:	characteristic
Odour Threshold	:	Not applicable
pH	:	Not applicable
Melting point	:	> 90 °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	:	To the best of our current knowledge, no thermal decomposition of the product is expected if it is processed according to good manufacturing practices. See section 10.4. "Conditions to avoid"
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	:	No dangerous reaction known under conditions of normal use.

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 and sources of ignition.
Incompatible materials	:	no data available Strong acids and strong bases Strong acids and oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products if stored and handled as prescribed

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

None known.

Acute toxicity

Product:

Acute dermal toxicity	:	Acute toxicity estimate: 2,540 mg/kg Method: Calculation method

Components:

N,N'-Ethylenedi(stearamide):

Acute oral toxicity	:	LD50 (Rat, male and female): > 5,000 mg/kg Method: OECD Test Guideline 401
Acute inhalation toxicity	:	LC50 (Rat, male and female): > 6.3 mg/l Test atmosphere: dust/mist Method: OECD Test Guideline 403
Acute dermal toxicity	:	LD50 (Rabbit, male and female): > 2,000 mg/kg Method: OECD Test Guideline 402

Amorphous silicon dioxide:

Acute oral toxicity	:	LD50 (Rat, male and female): > 5,000 mg/kg Method: OECD Test Guideline 401 GLP: yes Remarks: No significant adverse effects were reported
Acute inhalation toxicity	:	LC50 (Rat, male and female): > 2.08 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.

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Method: Other
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

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

Skin corrosion/irritation

Product:

Result: No skin irritation

Components:

N,N'-Ethylenedi(stearamide):

Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

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

C.I. Pigment White 6:

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

Serious eye damage/eye irritation

Product:

Result: No eye irritation

Components:

N,N'-Ethylenedi(stearamide):

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

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

C.I. Pigment White 6:

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

Respiratory or skin sensitisation

Product:

Result: non-sensitizing

Components:

N,N'-Ethylenedi(stearamide):

Species: Mouse
Method: OECD Test Guideline 429
Result: Not a skin sensitizer.

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

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.

Germ cell mutagenicity

Components:

N,N'-Ethylenedi(stearamide):

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster lung cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: negative

Test Type: Mammalian cell gene mutation assay
Test system: mouse lymphoma cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative

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

Amorphous silicon dioxide:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Concentration: 667 - 10000 µg/plate
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: In vitro gene mutation study in mammalian cells
Test system: Chinese hamster ovary cells
Concentration: 10 - 500 µg/ml
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: yes

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Concentration: 38 - 1000 µg/ml
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: negative
GLP: yes

Genotoxicity in vivo : Test Type: Cytogenetic assay
Species: Rat (male)
Strain: Fischer F344
Application Route: Inhalation
Exposure time: 13 w, 6 h/d, 5 d/wk
Dose: ca. 50 mg/m3
Method: Other
Result: negative
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
Test system: mouse lymphoma cells
Concentration: 5, 10, 20, 40, 60, 80, 100 an
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: 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.

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

Carcinogenicity

Components:

N,N'-Ethylenedi(stearamide):

Carcinogenicity - Assessment : No information available.

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.

C.I. Pigment White 6:

Carcinogenicity - Assessment : Not classifiable as a human carcinogen.

Reproductive toxicity

Components:

N,N'-Ethylenedi(stearamide):

Effects on foetal development : Test Type: Pre-natal
Species: Rat
Strain: Sprague-Dawley
Application Route: oral (gavage)
General Toxicity Maternal: NOAEL: >= 1,000 mg/kg body weight
Method: OECD Test Guideline 414

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.

C.I. Pigment White 6:

Effects on fertility : Remarks: no data available

Effects on foetal development : Test Type: Pre-natal
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.

STOT - single exposure

Components:

N,N'-Ethylenedi(stearamide):

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.

C.I. Pigment White 6:

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

STOT - repeated exposure

Components:

N,N'-Ethylenedi(stearamide):

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.

C.I. Pigment White 6:

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

Repeated dose toxicity

Components:

N,N'-Ethylenedi(stearamide):

Species: Rat, male and female
NOEL: >= 1000 mg/kg bw/day
Application Route: oral (gavage)
Method: OECD Test Guideline 408

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.

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

Aspiration toxicity

Components:

N,N'-Ethylenedi(stearamide):

no data available

Amorphous silicon dioxide:

No aspiration toxicity classification

Aluminium hydroxide:

No aspiration toxicity classification

C.I. Pigment White 6:

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:

N,N'-Ethylenedi(stearamide):

Toxicity to fish : LC50 (Oryzias latipes (Orange-red killifish)): 0.027 mg/l
End point: mortality
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.0022 mg/l
Exposure time: 48 h
Test Type: semi-static test
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (algae)): 0.053 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity) : Remarks: no data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC50 (Daphnia magna (Water flea)): 0.0056 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l
Exposure time: 3 h
Test Type: static test
Method: OECD Test Guideline 209

Toxicity to soil dwelling organisms	:	NOEC (Eisenia fetida (earthworms)): >= 1,000 mg/kg Exposure time: 56 d Method: OECD Test Guideline 222
Sediment toxicity	:	NOEC: >= 1000 mg/kg dry weight (d.w.) Test Type: static test Sediment: Artificial sediment Exposure duration: 28 d Method: OECD Test Guideline 218

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 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.
Sediment toxicity	:	LC50: 148.41 mg/l Duration: 14 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.

Aluminium hydroxide:

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

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 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
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

Persistence and degradability

Components:

N,N'-Ethylenedi(stearamide):

Biodegradability : aerobic

Inoculum: activated sludge
Carbon dioxide (CO2)
Result: Not readily biodegradable.
Biodegradation: 5.5 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Amorphous silicon dioxide:

Biodegradability : Remarks: Not applicable

Aluminium hydroxide:

Biodegradability : Remarks: Not applicable

C.I. Pigment White 6:

Biodegradability : Remarks: Not applicable for inorganic compound.

Bioaccumulative potential

Product:

Bioaccumulation : Remarks: not tested.

Components:

N,N'-Ethylenedi(stearamide):

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

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

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

Mobility in soil

Product:

Distribution among environmental compartments : Remarks: not tested.

Components:

N,N'-Ethylenedi(stearamide):

Distribution among environmental compartments : log Koc: 8.6 - 8.91
Method: calculated

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

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:

N,N'-Ethylenedi(stearamide):

Results of PBT and vPvB assessment : The substance is not identified as a PBT or as a vPvB substance.

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.

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.

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

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
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 QC OEL / TWAEV	:	Time-weighted average exposure value
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; 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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