

## 1. Identification

<b>Product identifier</b>	<b>VALTREX CAPLETS</b>
<b>Other means of identification</b>	Not available.
<b>Synonym(s)</b>	VALTREX CAPLETS 500 MG * VALTREX CAPLETS 1 G * VALTREX TABLETS 500 MG * VALTREX S TABLETS 500 MG * RAPIVIR TABLETS * ZELITREX TABLETS * VALACYCLOVIR HYDROCHLORIDE, FORMULATED PRODUCT
<b>Recommended use</b>	Medicinal Product  This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.
<b>Recommended restrictions</b>	No other uses are advised.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Manufacturer</b>	

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available 24 hrs/7 days; multi-language response

## 2. Hazard(s) identification

### Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

## 3. Composition/information on ingredients

### Mixtures

<b>Hazardous components</b>			
<b>Chemical name</b>	<b>Common name and synonyms</b>	<b>CAS number</b>	<b>%</b>
VALACYCLOVIR HYDROCHLORIDE	VALACYCLOVIR VALACICLOVIR VALACICLOVIR HYDROCHLORIDE 2-((2-AMINO-1,6-DIHYDRO-6 OXO-9H-PURIN-9-YL)METHOXY)ETHYL-L- HYDROCHLORIDE GW282358X 256U87 1479 (GW ACN)	124832-27-5	70 - < 80
POLYVINYLPIRROLIDONE	CROSPVIDONE CROSPVIDONE (KOLLIDON CL-SF) PVPP POLY[1-(2-OXO-1-PYRROLIDINYL)-1,2-ETH	25249-54-1	3 - < 5

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
POLYVINYLPIRROLIDONE	2-PYRROLIDINONE, 1-ETHENYL, HOMOPOLYMER 1-ETHENYL-2-PYRROLIDINONE HOMOPOLYMER 2-PYRROLIDINONE, 1-VINYL-, POLYMERS 1-VINYL-2-PYRROLIDINONE POLYMERS POLY(VINYLPYRROLIDINONE) POLY(N-VINYLPYRROLIDINONE) POLY(1-VINYLPYRROLIDINONE) POLY(VINYLPYRROLIDONE) POLY(N-VINYLPYRROLIDONE) POVIDONE PVP VINYLPYRROLIDINONE POLYMER N-VINYLPYRROLIDINONE POLYMER N-VINYLPYRROLIDONE HOMOPOLYMER VINYLPYRROLIDONE POLYMER N-VINYLPYRROLIDONE POLYMER RTECS TR8370000 PLASDONE PLASDONE K29/32 POLY-1-VINYL-2-PYRROLIDON POLYVINYL-PYRROLIDONE PROVIDONE	9003-39-8	1 - < 3
TITANIUM DIOXIDE	ANATASE BROOKITE RUTILE TITANIUM OXIDE TITANIUM DIOXIDE (TiO2) C.I. PIGMENT WHITE 6 C.I. 77891 TITANIUM(IV) OXIDE TITANIUM(4+) OXIDE TITANIUM PEROXIDE (TiO2) TITANIA (TiO2) PIGMENT WHITE 6 TITANIA KRONOS TITANIC OXIDE O2Ti OHS23510 RTECS XR2275000 DIOXIDO DE TITANIO TITANOKSIIID	13463-67-7	1 - < 3
MAGNESIUM STEARATE	OCTADECANOIC ACID, MAGNESIUM SALT STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE OCTADECANOIC ACID MAGNESIUM SALT MAGNESIUM OCTADECANOATE C36H70MGO4 OHS13505 RTECS WI4390000 MAGNESIUMDISTEARAT	557-04-0	< 1
SILICON DIOXIDE COLLOIDAL		7631-86-9	< 0.3
Other components below reportable levels			10 - < 20

\*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

#### 4. First-aid measures

<b>Inhalation</b>	If not breathing, give artificial respiration. If breathing is difficult, trained personnel should give oxygen. Get medical attention immediately.
<b>Skin contact</b>	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Remove and isolate contaminated clothing and shoes. Get medical attention if symptoms occur.
<b>Eye contact</b>	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

<b>Most important symptoms/effects, acute and delayed</b>	Possible effects of overexposure in the workplace include: headache; nausea.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire-fighting equipment/instructions</b>	In the event of fire, cool tanks with water spray.
<b>Specific methods</b>	Cool containers exposed to flames with water until well after the fire is out.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the MSDS.
<b>Methods and materials for containment and cleaning up</b>	Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13 of the MSDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Avoid prolonged exposure. Observe good industrial hygiene practices.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the MSDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

<b>GSK Components</b>	<b>Type</b>	<b>Value</b>	
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1	
VALACYCLOVIR HYDROCHLORIDE (CAS 124832-27-5)	8 HR TWA	5000 mcg/m3	
	OHC	1	
<b>US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)</b>			
<b>Components</b>	<b>Type</b>	<b>Value</b>	<b>Form</b>
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	15 mg/m3	Total dust.
<b>US. OSHA Table Z-3 (29 CFR 1910.1000)</b>			
<b>Components</b>	<b>Type</b>	<b>Value</b>	
SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)	TWA	0.8 mg/m3	
		20 millions of particle	
<b>US. ACGIH Threshold Limit Values</b>			
<b>Components</b>	<b>Type</b>	<b>Value</b>	
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	10 mg/m3	

**US. NIOSH: Pocket Guide to Chemical Hazards****Components****Type****Value**SILICON DIOXIDE  
COLLOIDAL (CAS  
7631-86-9)

TWA

6 mg/m3

**Biological limit values**

No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls**

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

**Individual protection measures, such as personal protective equipment****Eye/face protection**

If contact is likely, safety glasses with side shields are recommended.

**Hand protection**

For prolonged or repeated skin contact use suitable protective gloves. The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.

**Other**

Wear suitable protective clothing.

**Respiratory protection**

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

**Thermal hazards**

Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations**

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

**9. Physical and chemical properties****Appearance****Physical state**

Solid.

**Form**

Tablet.

**Color**

Blue

**Odor**

Not available.

**Odor threshold**

Not available.

**pH**

Not available.

**Melting point/freezing point**

Not available.

**Initial boiling point and boiling range**

Not available.

**Flash point**

Not available.

**Evaporation rate**

Not available.

**Flammability (solid, gas)**

Not available.

**Upper/lower flammability or explosive limits****Flammability limit - lower (%)**

Not available.

**Flammability limit - upper (%)**

Not available.

**Explosive limit - lower (%)**

Not available.

**Explosive limit - upper (%)**

Not available.

**Vapor pressure**

Not available.

**Vapor density**

Not available.

**Relative density**

Not available.

**Solubility(ies)**

Not available.

**Partition coefficient (n-octanol/water)**

Not available.

**Auto-ignition temperature**

Not available.

**Decomposition temperature**

Not available.

**Viscosity**

Not available.

**10. Stability and reactivity****Reactivity**

The product is stable and non-reactive under normal conditions of use, storage and transport.

<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents. Fluorine.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Ingestion</b>	Based on available data, the classification criteria are not met. Health injuries are not known or expected under normal use.
<b>Inhalation</b>	No adverse effects due to inhalation are expected.
<b>Skin contact</b>	Based on available data, the classification criteria are not met. Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Based on available data, the classification criteria are not met. Direct contact with eyes may cause temporary irritation.

<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	The following adverse effects have been noted with therapeutic use of this material: headache; nausea.
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### Information on toxicological effects

<b>Acute toxicity</b>	Based on available data, the classification criteria are not met. Health injuries are not known or expected under normal use.
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Components	Species	Test Results
MAGNESIUM STEARATE (CAS 557-04-0)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
POLYVINYLPIRROLIDONE (CAS 9003-39-8)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
TITANIUM DIOXIDE (CAS 13463-67-7)		
<b>Acute</b>		
<i>Inhalation</i>		
LC50	Rat	6820 mcg/m3
<i>Oral</i>		
LD50	Rat	> 24 g/kg
<b>Chronic</b>		
<i>Inhalation</i>		
LOEC	Rat	8.6 mg/m3, 1 years, TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years, Highest dose 5 mg/m3, 24 months
<b>Subacute</b>		
<i>Inhalation</i>		
LOEL	Rat	0.1 - 35 mg/m3, 4 weeks, Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.
NOAEC	Guinea pig	26 mg/m3, 3 weeks, No evidence of significant inflammation in respiratory tract.
<i>Oral</i>		
NOAEL	Rat	100000 ppm, 14 Day, Dietary study, highest dose tested.

Components	Species	Test Results
<b>Subchronic</b> <i>Inhalation</i> LOEC	Rat	3.2 - 20 mg/m <sup>3</sup> , 8 min, Accumulation of TiO <sub>2</sub> in macrophages and evidence of pulmonary inflammation.
VALACYCLOVIR HYDROCHLORIDE (CAS 124832-27-5)		
<b>Acute</b> <i>Oral</i> LD50	Rat	> 5000 mg/kg
<b>Chronic</b> <i>Oral</i> NOAEL	Rat	50 mg/kg/day
* Estimates for product may be based on additional component data not shown.		
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met. Health injuries are not known or expected under normal use.	
<b>Irritation Corrosion - Skin</b> VALACYCLOVIR HYDROCHLORIDE	Acute dermal irritation; OECD 404 Result: Negative Species: Rabbit	
TITANIUM DIOXIDE	Acute dermal irritation; OECD 404, Literature data Result: Non-irritant Species: Rabbit Literature data Result: Non-irritant Species: Guinea pig Literature data Result: Non-irritant Species: Human	
<b>Irritation Corrosion - Skin: P.I.I. value</b> MAGNESIUM STEARATE	0	
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met. Direct contact with eyes may cause temporary irritation.	
<b>Eye</b> VALACYCLOVIR HYDROCHLORIDE	Acute ocular irritation; OECD 405, Kay and Calandra score = 4; maximum group mean score = 12 Result: Mild irritant Species: Rabbit IRE Assay Result: Negative; not likely to be a severe irritant Species: Rabbit	
TITANIUM DIOXIDE	OECD 405, Literature data Result: Mild irritant Species: Rabbit	
<b>Eye / Kay and Calandra class - Intact</b> MAGNESIUM STEARATE	4 Recovery Period: 2 days	
<b>Respiratory sensitization</b>	Due to lack of data the classification is not possible.	
<b>Skin sensitization</b>	Based on available data, the classification criteria are not met. This product is not expected to cause skin sensitization.	
<b>Sensitization</b> TITANIUM DIOXIDE	5 % Optimisation Test, Literature data - Vehicle: petrolatum Result: Negative Species: Guinea pig Test Duration: 48 hour exposure	
VALACYCLOVIR HYDROCHLORIDE	Method not specified, Acyclovir tested; read across to valacyclovir Result: Negative Species: Guinea pig	
TITANIUM DIOXIDE	Patch test, Literature data Result: Negative Species: Human	
<b>Germ cell mutagenicity</b> VALACYCLOVIR HYDROCHLORIDE	Based on available data, the classification criteria are not met. Ames Assay, GLP assay Result: Negative	

TITANIUM DIOXIDE	Ames, Literature data Result: Negative
VALACYCLOVIR HYDROCHLORIDE	Chromosomal Aberration Assay In Vitro, human lymphocytes Result: Negative Chromosomal Aberration Assay In Vivo, bone marrow, Maximum dose = 3000 mg/kg Result: Negative Species: Rat GreenScreen Assay Result: Positive (+ S9 only)
TITANIUM DIOXIDE	Micronucleus Assay in vitro, CHO cells, Literature data Result: Negative Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data Result: Positive
VALACYCLOVIR HYDROCHLORIDE	Micronucleus Assay, GLP assay; positive result at maximum dose (500 mg/kg), negative study result at 250 mg/kg Result: Positive Species: Mouse Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay Result: Positive (+ S9 only)
TITANIUM DIOXIDE	Syrian Hamster Embryo (SHE) cell transformation assay Result: Negative WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data Result: Positive
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met. Contains a material (titanium dioxide) classified as a carcinogen by external agencies. Carcinogenic activity was seen in inhalation studies using laboratory animals. High concentrations or doses administered over an extended period of time were required to produce adverse effects.
TITANIUM DIOXIDE	0.5 mg/m3, Literature data Result: Negative Species: Rat Test Duration: 24 months 0.72 - 14.8 mg/m3, Literature data Result: Negative Species: Mouse 10 - 250 mg/m3, Dietary study - Literature data. Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration. Species: Rat Test Duration: 24 months
VALACYCLOVIR HYDROCHLORIDE	2 year bioassay, Maximum dose = 100 mg/kg/day Result: Negative Species: Rat 2 year bioassay, Maximum dose = 120 mg/kg/day Result: Negative Species: Mouse
TITANIUM DIOXIDE	25000 - 50000 ppm, Dietary study Result: Negative Species: Mouse 25000 - 50000 ppm, Dietary study - Literature data. Result: Negative Species: Rat 7.2 - 14.8 mg/m3, Literature data Result: Lung tumour Species: Rat Test Duration: 24 months
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>	
POLYVINYLPIRROLIDONE (CAS 9003-39-8)	3 Not classifiable as to carcinogenicity to humans.
SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)	3 Not classifiable as to carcinogenicity to humans.
TITANIUM DIOXIDE (CAS 13463-67-7)	2B Possibly carcinogenic to humans.
<b>Reproductive toxicity</b>	Based on available data, the classification criteria are not met.
VALACYCLOVIR HYDROCHLORIDE	Embryo-foetal development - Oral Result: Foetal NOAEL = 400 mg/kg/day (maximum dose); Maternal LOAEL = 200 mg/kg/day (decreased weight gain) Species: Rabbit Embryo-foetal development - Oral Result: Maternal and foetal toxicity (no evidence of malformations) with doses of 400 mg/kg/day (maximum dose) Species: Rat

Fertility  
 Result: NOAEL = 200 mg/kg/day (male and female), maximum dose  
 Species: Rat  
 Pre- and Post-natal development  
 Result: NOAEL = 200 mg/kg/day (maximum dose); no adverse foetal effects  
 Species: Rat

**Specific target organ toxicity - single exposure** Based on available data, the classification criteria are not met.

**Specific target organ toxicity - repeated exposure** Based on available data, the classification criteria are not met.

**Aspiration hazard** Not likely, due to the form of the product.

## 12. Ecological information

**Ecotoxicity** Not expected to be harmful to aquatic organisms.

Components		Species	Test Results
MAGNESIUM STEARATE (CAS 557-04-0)			
<b>Aquatic</b>			
<i>Acute</i>			
Fish	EC50	Orange-red killfish (Adult <i>Oryzias latipes</i> )	130 mg/l, 96 hours
Microtox	EC50	Microtox	12.5 mg/l, 15 minutes
POLYVINYLPOLYPYRROLIDONE (CAS 25249-54-1)			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours, Static test
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	84 mg/l, 48 hours, Static test
	NOEC	Water flea ( <i>Daphnia magna</i> )	32 mg/l, 48 hours, Static test
POLYVINYLPYRROLIDONE (CAS 9003-39-8)			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours, Static test
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	84 mg/l, 48 hours, Static test
	NOEC	Water flea ( <i>Daphnia magna</i> )	32 mg/l, 48 hours, Static test
SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)			
<b>Aquatic</b>			
<i>Acute</i>			
Algae	EC50	Green algae ( <i>Selenastrum capricornutum</i> )	440 mg/l, 72 hours
	NOEC	Green algae ( <i>Selenastrum capricornutum</i> )	60 mg/l, 72 hours
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	> 10000 mg/l, 24 hours, Static test
Fish	EC50	Common carp (Juvenile <i>Cyprinus carpio</i> )	> 10000 mg/l, 72 hours
		Zebra fish (Adult <i>Brachydanio rerio</i> )	5000 mg/l, 96 hours, Static test
Microtox	EC50	Microtox	8700 mg/l, 15 minutes
TITANIUM DIOXIDE (CAS 13463-67-7)			
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	> 1000 mg/l, 48 hours, Static test
VALACYCLOVIR HYDROCHLORIDE (CAS 124832-27-5)			
<b>Aquatic</b>			
<i>Acute</i>			
Activated Sludge Respiration	IC50	Residential sludge	> 100 mg/l, 3 hours, OECD 209
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	340 mg/l, 48 hours, Static test

Components		Species	Test Results
	NOEC	Water flea (Daphnia magna)	56 mg/l, 48 hours, Static test
Microtox	MIC	Aspergillus flavus	> 1000 mg/l
		Azotobacter chroococcum	> 1000 mg/l
		Chaetomium globosum	> 1000 mg/l
		Nostoc sp.	> 1000 mg/l
		Pseudomonas fluorescens	> 1000 mg/l

\* Estimates for product may be based on additional component data not shown.

#### Persistence and degradability

##### Photolysis

###### Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated

###### UV/visible spectrum wavelength

MAGNESIUM STEARATE 210 nm

VALACYCLOVIR HYDROCHLORIDE 264

##### Hydrolysis

###### Half-life (Hydrolysis-acidic)

VALACYCLOVIR HYDROCHLORIDE 68.38 Days Measured

###### Half-life (Hydrolysis-basic)

VALACYCLOVIR HYDROCHLORIDE 15.13 Hours Measured

###### Half-life (Hydrolysis-neutral)

VALACYCLOVIR HYDROCHLORIDE 55.92 Hours Measured

##### Biodegradability

###### Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE 50 %, 13 days

#### Bioaccumulative potential

##### Partition coefficient n-octanol / water (log Kow)

VALACYCLOVIR HYDROCHLORIDE < 1

##### Bioconcentration factor (BCF)

MAGNESIUM STEARATE > 9999 Estimated

#### Mobility in soil

##### Adsorption

###### Soil/sediment sorption - log Koc

MAGNESIUM STEARATE 5.86 Estimated

**Other adverse effects** Not available.

### 13. Disposal considerations

**Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

**Hazardous waste code** The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Waste from residues / unused products** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### 14. Transport information

#### DOT

Not regulated as a dangerous good.

#### IATA

Not regulated as a dangerous good.

#### IMDG

Not regulated as a dangerous good.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

## 15. Regulatory information

### US federal regulations

#### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

#### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

#### US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

#### SARA 304 Emergency release notification

Not regulated.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

<b>Hazard categories</b>	Immediate Hazard - No Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
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<b>SARA 302 Extremely hazardous substance</b>	No
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<b>SARA 311/312 Hazardous chemical</b>	No
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<b>NFPA ratings</b>	Health: 1 Flammability: 1 Instability: 0
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<b>HMIS® ratings</b>	Health: 1* Flammability: 1 Physical hazard: 0
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### Other federal regulations

#### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

#### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

<b>Safe Drinking Water Act (SDWA)</b>	Not regulated.
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<b>Food and Drug Administration (FDA)</b>	Not regulated.
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### US state regulations

#### US. Massachusetts RTK - Substance List

SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)

TITANIUM DIOXIDE (CAS 13463-67-7)

#### US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

#### US. Pennsylvania RTK - Hazardous Substances

SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)

TITANIUM DIOXIDE (CAS 13463-67-7)

#### US. Rhode Island RTK

Not regulated.

#### US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer.

#### US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

TITANIUM DIOXIDE (CAS 13463-67-7)

Listed: September 2, 2011

### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)  
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

<b>Issue date</b>	12-12-2013
<b>Revision date</b>	12-12-2013
<b>Version #</b>	13
<b>Further information</b>	HMIS® is a registered trade and service mark of the NPCA.
<b>HMIS® ratings</b>	Health: 1* Flammability: 1 Physical hazard: 0
<b>NFPA ratings</b>	Health: 1 Flammability: 1 Instability: 0
<b>References</b>	GSK Hazard Determination
<b>Disclaimer</b>	The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.
<b>Revision Information</b>	Composition / Information on Ingredients: Disclosure Overrides Other information, including date of preparation or last revision: Further information