



# SAFETY DATA SHEET

## 1. Identification

**Product identifier** ZANTAC TABLETS

**Other means of identification**

**Synonyms**

ZANTAC 150 TABLETS \* ZANTAC 300 TABLETS \* ANAK TABLETS \* AZANTAC TABLETS \* SOSTRIL TABLETS \* ZANDINE TABLETS \* ZANTIC TABLETS \* ZINETAC TABLETS \* RANITIDINE HYDROCHLORIDE, FORMULATED PRODUCT

**Recommended use** 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.

**Recommended restrictions** No other uses are advised.

**Manufacturer/Importer/Supplier/Distributor information**

**Manufacturer**

GlaxoSmithKline US  
5 Moore Drive  
Research Triangle Park, NC 27709 USA  
US General Information (normal business hours): +1-888-825-5249  
Email Address: msds@gsk.com  
Website: www.gsk.com  
EMERGENCY PHONE NUMBERS -  
TRANSPORT EMERGENCIES::  
US / International toll call +1 703 527 3887  
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**

Chemical name	Common name and synonyms	CAS number	%
RANITIDINE HYDROCHLORIDE	AH 19065AB * N,N-DIMETHYL-5-(2-(1-METHYLAMINO-2-NITROVINYLAMINO)ETHYLTHIOMETHYL)FURFURYL AMINE HYDROCHLORIDE * 54 (GW ACN)	66357-59-3	50 - < 60
MICROCRYSTALLINE CELLULOSE	AVICEL PH MICROCRYSTALLINE CELLULOSE * ALPHA-CELLULOSE * AVICEL PH101 * AVICEL PH102 * AVICEL PH103 * AVICEL PH105 * AVICEL PH112 * AVICEL PH200 * CELLULOSE (8CI9CI) * CELLULOSE CRYSTALLINE * CELLULOSE, FOOD GRADE * CRYSTALLINE CELLULOSE	9004-34-6	15 - < 45

Chemical name	Common name and synonyms	CAS number	%
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT * MAGNESIUM DISTEARATE * DIBASIC MAGNESIUM STEARATE * MAGNESIUM DISTEARATE, PURE	557-04-0	0.1 - < 5
TITANIUM DIOXIDE	TITANIUM OXIDE * TITANIUM(IV) OXIDE * TITANIUM PEROXIDE (TiO2) * PIGMENT WHITE 6	13463-67-7	<5
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>	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
<b>Most important symptoms/effects, acute and delayed</b>	Accidental exposure or contact might produce: Irritation of eyes and mucous membranes. Sensitization. Skin irritation. May cause an allergic skin reaction. Dermatitis. Rash. The following adverse effects have been noted with therapeutic use of this material: decrease in heart rate; decrease in blood pressure; temporary decrease in white blood cell counts; coughing; increased mucous secretion.
<b>Indication of immediate medical attention and special treatment needed</b>	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
<b>General information</b>	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). 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. 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>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

#### 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. Wear protective clothing and equipment consistent with the degree of hazard. 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 SDS.
<b>Methods and materials for containment and cleaning up</b>	Collect and place it in a suitable, properly labelled container for recovery or disposal. 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 SDS. No specific decontamination or detoxification procedures have been identified for this product.
<b>Environmental precautions</b>	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

#### 7. Handling and storage

<b>Precautions for safe handling</b>	Avoid prolonged exposure. Avoid breaking or crushing tablets.
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**Conditions for safe storage, including any incompatibilities**

Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

**8. Exposure controls/personal protection****Occupational exposure limits****GSK**

Components	Type	Value	Note
RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)	15 MIN STEL	50 mcg/m3	SKIN SENSITISER
	OHC	50 mcg/m3 3	RESPIRATORY SENSITISER

**US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	PEL	5 mg/m3	Respirable fraction.
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	15 mg/m3 15 mg/m3	Total dust. Total dust.

**US. ACGIH Threshold Limit Values**

Components	Type	Value
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	10 mg/m3

**US. NIOSH: Pocket Guide to Chemical Hazards**

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total

**Biological limit values**

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

**Exposure guidelines****Appropriate engineering controls**

General ventilation normally adequate.

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

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

**Skin protection****Hand protection**

Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

**Other**

Wear suitable protective clothing as protection against splashing or contamination.

**Respiratory protection**

No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

**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**

<b>Physical state</b>	Solid.
<b>Form</b>	Tablet.
<b>Color</b>	Not available.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	This product is expected to be stable.
<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>	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard. Prolonged inhalation may be harmful.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use.
<b>Ingestion</b>	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.

<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	Accidental exposure or contact might produce: Irritation of eyes and mucous membranes. Sensitization. Skin irritation. Dermatitis. May cause an allergic skin reaction. Rash. The following adverse effects have been noted with therapeutic use of this material: decrease in heart rate; decrease in blood pressure; temporary decrease in white blood cell counts; coughing; increased mucous secretion.
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### Information on toxicological effects

**Acute toxicity** May be harmful if swallowed.

<b>Components</b>	<b>Species</b>	<b>Test Results</b>
MAGNESIUM STEARATE (CAS 557-04-0)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
<b>Acute</b>		
<i>Dermal</i>		
LD50	Rabbit	> 2000 mg/kg
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 1000 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.
<b>Subchronic</b>		
<i>Inhalation</i>		
LOEC	Rat	3.2 - 20 mg/m3, 8 min Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.

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

**Skin corrosion/irritation** Health injuries are not known or expected under normal use.

**Irritation Corrosion - Skin**

TITANIUM DIOXIDE

0, Literature data  
Result: Non-irritant  
Species: Guinea pig  
0, Literature data  
Result: Non-irritant  
Species: Human

**Irritation Corrosion - Skin**

TITANIUM DIOXIDE

Acute dermal irritation; OECD 404, Literature data

Result: Non-irritant

Species: Rabbit

RANITIDINE HYDROCHLORIDE

Acute dermal irritation; OECD 404, Primary dermal irritation index = 0

Result: Negative

Species: Rabbit

**Irritation Corrosion - Skin: P.I.I. value**

MAGNESIUM STEARATE

0

**Serious eye damage/eye irritation**

Direct contact with eyes may cause temporary irritation.

**Eye**

RANITIDINE HYDROCHLORIDE

Acute ocular irritation; OECD 405, Kay and Calandra score = 3

Result: Minimal 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

**Eye / Kay and Calandra class - Intact**

MAGNESIUM STEARATE

4

Recovery Period: 2 days

**Respiratory or skin sensitization****Respiratory sensitization**

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

RANITIDINE HYDROCHLORIDE

Occupational exposure

Result: Positive

Species: Human

**Skin sensitization**

May cause an allergic skin reaction.

**Sensitization**

TITANIUM DIOXIDE

5 % Optimisation Test, Literature data - Vehicle: petrolatum

Result: Negative

Species: Guinea pig

Test Duration: 48 hour exposure

RANITIDINE HYDROCHLORIDE

Occupational exposure

Result: Positive

Species: Human

Optimisation Test

Result: Weak sensitiser

Species: Guinea pig

TITANIUM DIOXIDE

Patch test, Literature data

Result: Negative

Species: Human

**Germ cell mutagenicity**

No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

**Mutagenicity**

RANITIDINE HYDROCHLORIDE

Ames Assay, GLP assay

Result: Negative

TITANIUM DIOXIDE

Ames, Literature data

Result: Negative

RANITIDINE HYDROCHLORIDE

Chromosomal Aberration Assay In Vitro, human

lymphocytes, Ranitidine bismuth citrate tested

Result: Positive

Chromosomal Aberration Assay In Vivo; germ cells,

Maximum dose = 1000 mg/kg

Result: Negative

Species: Mouse

GreenScreen Assay

Result: Negative

TITANIUM DIOXIDE

Micronucleus Assay in vitro, CHO cells, Literature data

Result: Negative

**Mutagenicity**

TITANIUM DIOXIDE

Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data

Result: Positive

RANITIDINE HYDROCHLORIDE

Micronucleus Test

Result: Negative

Species: Rat

Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay

Result: Negative

SOS/umu Assay

Result: Negative

TITANIUM DIOXIDE

Syrian Hamster Embryo (SHE) cell transformation assay

Result: Negative

RANITIDINE HYDROCHLORIDE

Unscheduled DNA Synthesis in vivo, Maximum dose = 200 mg/kg

Result: Negative

Species: Rat

Organ: Stomach

TITANIUM DIOXIDE

WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data

Result: Positive

RANITIDINE HYDROCHLORIDE

Yeast Mutation Assay

Result: Negative

**Carcinogenicity**

Carcinogenic effects are not expected as a result of occupational exposure.

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

RANITIDINE HYDROCHLORIDE

2 year bioassay, Maximum dose = 2000 mg/kg/day

Result: Negative

Species: Mouse

2 year bioassay, Maximum dose = 2000 mg/kg/day

Result: Negative

Species: Rat

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

**IARC Monographs. Overall Evaluation of Carcinogenicity**

TITANIUM DIOXIDE (CAS 13463-67-7)

2B Possibly carcinogenic to humans.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Reproductive toxicity**

Contains no ingredient listed as toxic to reproduction

**Reproductivity**

RANITIDINE HYDROCHLORIDE

Embryo-foetal development - Oral

Result: Foetal NOAEL = 100 mg/kg/day (maximum dose);

Maternal NOAEL = 25 mg/kg/day (decreased weight gain at 50 and 100 mg/kg/day)

Species: Rat

Embryo-foetal development - Oral

Result: NOAEL = 100 mg/kg/day (maximum dose)

Species: Rabbit

**Reproductivity**  
RANITIDINE HYDROCHLORIDE

Fertility  
Result: NOAEL / fertility = 100 mg/kg/day (male) and 200 mg/kg/day (female) (maximum doses)  
Species: Rat

**Specific target organ toxicity - single exposure** None known.  
**Specific target organ toxicity - repeated exposure** None known.  
**Aspiration hazard** Not available.  
**Chronic effects** Prolonged inhalation may be harmful. Prolonged exposure may cause chronic effects.  
**Further information** Occupational exposure to the substance or mixture may cause adverse effects.

**12. Ecological information**

**Ecotoxicity** No information is available about the potential of this product to produce adverse environmental effects. The product contains a substance which may cause long-term adverse effects in the environment.

Components	Species	Test Results
<b>MAGNESIUM STEARATE (CAS 557-04-0)</b>		
<b>Aquatic</b>		
<i>Acute</i>		
Fish	EC50	Orange-red killfish (Adult Oryzias latipes) 130 mg/l, 96 hours
<b>RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)</b>		
<b>Aquatic</b>		
<i>Acute</i>		
Activated Sludge Respiration	IC50	Residential sludge > 1000 mg/l, 3 hours OECD 209
Algae	EC50	Green algae (Selenastrum capricornutum) 167 mg/l, 72 hours OECD 201
	NOEC	Green algae (Selenastrum capricornutum) 56 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna) 730 mg/l, 48 hours Static test, OECD 202
	NOEC	Water flea (Daphnia magna) 347 mg/l, 48 hours Static test
Fish	EC50	Rainbow trout (Juvenile Oncorhynchus mykiss) > 112 mg/l, 14 days Flow-through test, OECD 203
	NOEC	Rainbow trout (Juvenile Oncorhynchus mykiss) 112 mg/l, 14 days Flow-through test
<i>Chronic</i> Crustacea	LOEC	Water flea (Ceriodaphnia dubia) 100 mg/l, 8 days Static renewal test, EPA 1002
	NOEC	Water flea (Ceriodaphnia dubia) 32 mg/l, 8 days
<b>TITANIUM DIOXIDE (CAS 13463-67-7)</b>		
<b>Aquatic</b>		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) > 1000 mg/l, 48 hours Static test

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

**Persistence and degradability**

**Photolysis**

**Half-life (Photolysis-aqueous)**

RANITIDINE HYDROCHLORIDE 70 Minutes Measured, Lake water

**Half-life (Photolysis-atmospheric)**

MAGNESIUM STEARATE 17 Hours Estimated



## Photolysis

### UV/visible spectrum wavelength

MAGNESIUM STEARATE	210 nm
RANITIDINE HYDROCHLORIDE	313 nm Measured, pH 7

## Hydrolysis

### Half-life (Hydrolysis-neutral)

RANITIDINE HYDROCHLORIDE	> 1 Years Measured
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## Biodegradability

### Percent degradation (Aerobic biodegradation-inherent)

MAGNESIUM STEARATE	77 %, 28 days BOD
RANITIDINE HYDROCHLORIDE	2 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge 43 %, 28 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

### Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE	50 %, 13 days
RANITIDINE HYDROCHLORIDE	3 - 10 %, 67 days

### Percent degradation (Anaerobic biodegradation)

RANITIDINE HYDROCHLORIDE	12 %, 35 days
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## Bioaccumulative potential

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

RANITIDINE HYDROCHLORIDE	0.0815
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### Bioconcentration factor (BCF)

MAGNESIUM STEARATE	> 9999 Estimated
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## Mobility in soil

### Adsorption

#### Soil/sediment sorption - log Koc

MAGNESIUM STEARATE	5.86 Estimated
RANITIDINE HYDROCHLORIDE	2.51 - 4.49, pH 5-7

## Mobility in general

### Volatility

#### Henry's law

RANITIDINE HYDROCHLORIDE	0 atm m <sup>3</sup> /mol, 24 C Estimated
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### Distribution

#### Octanol/water distribution coefficient log DOW

RANITIDINE HYDROCHLORIDE	-1.09, pH 7 -2.5, pH 5 0.14, pH 9
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**Other adverse effects** Not available.

## 13. Disposal considerations

### Disposal instructions

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

### 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). Avoid discharge into water courses or onto the ground.

### 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 dangerous goods.

## IMDG

Not regulated as dangerous goods.

**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.

#### SARA 304 Emergency release notification

Not regulated.

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

Not listed.

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

**Hazard categories** Immediate Hazard - Yes  
Delayed Hazard - Yes  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

#### SARA 302 Extremely hazardous substance

Not listed.

**SARA 311/312 Hazardous chemical** No

#### SARA 313 (TRI reporting)

Not regulated.

### 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.

**Safe Drinking Water Act (SDWA)** Not regulated.

### US state regulations

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

#### US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

#### US. Massachusetts RTK - Substance List

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

TITANIUM DIOXIDE (CAS 13463-67-7)

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

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

TITANIUM DIOXIDE (CAS 13463-67-7)

#### US. Pennsylvania Worker and Community Right-to-Know Law

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

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
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>	11-07-2014
<b>Revision date</b>	11-07-2014
<b>Version #</b>	12
<b>Further information</b>	This material has not been assessed for HMIS or NFPA ratings.
<b>HMIS® ratings</b>	Health: 2* Flammability: 1 Physical hazard: 0
<b>NFPA ratings</b>	Health: 2 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>	This document has undergone significant changes and should be reviewed in its entirety.