SAFETY DATA SHEET

1. Identification

Product identifier **PIRITEZE ALLERGY TABLETS**

Other means of identification

Synonyms PIRITEZE ALLERGY TABLETS (UK) * PIRITEZE 10 MG TABLETS * MFC 00597 * CETIRIZINE DIHYDROCHLORIDE, 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	%
MICROCRYSTALLINE CELLULOSE	AVICEL PH MICROCRYSTALLINE CELLULOSE * ABICEL * ALPHA-CELLULOSE * ARBOCEL * ARBOCELL B 600/30 * ARBOCELL BC 200 * AVICEL PH101 * AVICEL PH102 * AVICEL PH103 * AVICEL PH105 * AVICEL PH112 * AVICEL PH200 * BETA-AMYLOSE * CELLEX MX * CELLULOSE (8CI9CI) * CELLULOSE 248 * CELLULOSE CRYSTALLINE * CELLULOSE, FOOD GRADE * CELUFI * CRYSTALLINE CELLULOSE * EMOCEL * MCC * MICROCRYSTALLINE CELLULOSE * POWDERED CELLULOSE * RTECS FJ5691460 * SOLKA FLOC BW200 * CELLULOSA (FIBRA PAPEL) * CELLULOSE (PAPER FIBRES) * CELLULOSE-PAPER FIBER * CELULOSA (FIBRA PAPEL) * TSELLULOOS	9004-34-6	33.0 - 34.0
CETIRIZINE DIHYDROCHLORIDE	ACETIC ACID, (2-(4-((4-CHLOROPHENYL)PHENYLMETHYL)-1-PIPERAZINYL)ET HOXY)-, DIHYDROCHLORIDE * (2-(4-((4-CHLOROPHENYL)PHENYLMETHYL)-1-PIPERAZINYL)ET HOXY)ACETIC ACID DIHYDROCHLORIDE	83881-52-1	8.0 - 9.0
HYDROXYPROPYL METHYL CELLULOSE	METHOCEL K4M * GONIOSOL * ISOPRO ALKALINE * METHOCEL E,F,K * METHOCEL HG * METHYL CELLULOSE PROPYLENE GLYCOL ETHER * HYPROMELLOSE * CELLULOSE, 2-HYDROXYPROPYL METHYL ESTER * METHYLHYDROXYPROPYLCELLULOSE * PHARMACOAT 603	9004-65-3	1.0 - 2.0
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT * MAGNESIUM DISTEARATE * DIBASIC MAGNESIUM STEARATE * MAGNESIUM DISTEARATE, PURE	557-04-0	<1.0
POLYETHYLENE GLYCOL 400	PEG 400 * ALPHA-HYDRO-OMEGA-HYDROXY-POLY(OXY-1,2-ETHANEDIYL) * PEG * CARBOWAX * POLYOXYETHYLENE 400 * CARBOWAX POLYETHYLENE GLYCOL 400 * CARBOWAX PEG 400 * OHS19121 * RTECS TQ3675000 * GLYCOLS, POLYETHYLENE * POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-HYDRO-.OMEGA. * POLYETHYLENEGLYCOL 6000 * POLYETHYLENGLYKOLE (PEG) (MOLMASSE 200-600)	25322-68-3	<1.0
SILICON DIOXIDE	SILICA * SILICA GEL * AMORPHOUS SILICA * DIATOMACEOUS EARTH * INFUSORIAL EARTH * CAB-O-SIL M-5	7631-86-9	<1.0
TITANIUM DIOXIDE	TITANIUM OXIDE * TITANIUM(IV) OXIDE * TITANIUM PEROXIDE (TiO2) * PIGMENT WHITE 6	13463-67-7	<1.0
Other components below reportable levels			50.0 - 55.0

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

4. First-aid measures

Inhalation

Under normal conditions of intended use, this material is not expected to be an inhalation hazard. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist.

Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	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.
Most important symptoms/effects, acute and delayed	The following adverse effects have been noted with therapeutic use of this material: dry mouth; drying of the nasal passages; drowsiness.
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire-fighting equipment/instructions	Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. Collect spillage. 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.
Environmental precautions	Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value
CETIRIZINE DIHYDROCHLORIDE (CAS 83881-52-1)	OHC	2
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)	OHC	1

GSK

Components	Type	Value
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	OHC	1
POLYETHYLENE GLYCOL 400 (CAS 25322-68-3)	OHC	1
SILICON DIOXIDE (CAS 7631-86-9)	OHC	1

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.
		15 mg/m3	Total dust.
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	15 mg/m3	Total dust.

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value
SILICON DIOXIDE (CAS 7631-86-9)	TWA	0.8 mg/m3
		20 mppcf

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
SILICON DIOXIDE (CAS 7631-86-9)	TWA	6 mg/m3	

US. AIHA Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
POLYETHYLENE GLYCOL 400 (CAS 25322-68-3)	TWA	10 mg/m3	Particulate.

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

Appropriate engineering controls An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended.

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

Skin protection

Other Not normally needed. 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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance	
Physical state	Solid.
Form	Tablet.
Color	White.
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)	
Solubility (water)	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	Not established.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents. Fluorine.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion	May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
Symptoms related to the physical, chemical and toxicological characteristics	The following adverse effects have been noted with therapeutic use of this material: dry mouth; drying of the nasal passages; drowsiness.

Information on toxicological effects

Acute toxicity May be harmful if swallowed. Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
CETIRIZINE DIHYDROCHLORIDE (CAS 83881-52-1)		
Acute		
Oral		
LD50	Rat	365 mg/kg
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 2000 mg/kg
POLYETHYLENE GLYCOL 400 (CAS 25322-68-3)		
Acute		
Oral		
LD50	Rat	30.2 g/kg
TITANIUM DIOXIDE (CAS 13463-67-7)		
Acute		
Inhalation		
LC50	Rat	6820 mcg/m3
Oral		
LD50	Rat	> 24 g/kg
Chronic		
Inhalation		
LOEC	Rat	8.6 mg/m3, 1 years TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophrages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years Highest dose
		5 mg/m3, 24 months

Components	Species	Test Results
Subacute		
Inhalation		
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.
Oral		
NOAEL	Rat	100000 ppm, 14 Day Dietary study, highest dose tested.
Subchronic		
Inhalation		
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
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

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

MAGNESIUM STEARATE
0

Serious eye damage/eye irritation Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

Eye

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 Not available.

Skin sensitization None known. This product is not expected to cause skin sensitization.

Maximisation assay (Magnusson and Kligman)

HYDROXYPROPYL METHYL CELLULOSE
Result: Negative
Species: Guinea pig

Sensitization

TITANIUM DIOXIDE
5 % Optimisation Test, Literature data - Vehicle: petrolatum
Result: Negative
Species: Guinea pig
Test Duration: 48 hour exposure
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

CETIRIZINE DIHYDROCHLORIDE
Ames
Result: Negative
Notes: FDA Approval Package

Mutagenicity

TITANIUM DIOXIDE	Ames, Literature data Result: Negative
CETIRIZINE DIHYDROCHLORIDE	Chromosomal Aberration Assay In Vitro, human lymphocytes Result: Negative Notes: FDA Approval Package In vivo Micronucleus Result: Negative Species: Mouse Notes: FDA Approval Package In vivo Micronucleus Result: Negative Species: Rat
TITANIUM DIOXIDE	Micronucleus Assay in vitro, CHO cells, Literature data Result: Negative Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data Result: Positive
CETIRIZINE DIHYDROCHLORIDE	Mouse Lymphoma Cell (L5178Y) Mutation Assay Result: Negative Notes: FDA Approval Package
TITANIUM DIOXIDE	Syrian Hamster Embryo (SHE) cell transformation assay Result: Negative WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data Result: Positive

Carcinogenicity Titanium Dioxide produced carcinogenic effects in a lifetime study in mice 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
CETIRIZINE DIHYDROCHLORIDE	16 mg/kg/day, Species-specific Result: Increase in benign tumours Species: Mouse Organ: Liver Notes: FDA Approval Package 20 mg/kg/day Result: Negative Species: Rat Notes: FDA Approval Package
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

SILICON DIOXIDE (CAS 7631-86-9)	3 Not classifiable as to carcinogenicity to humans.
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

CETIRIZINE DIHYDROCHLORIDE

135 mg/kg/day Embryo-foetal development
Result: Maternal toxicity; adverse foetal effects
Species: Rabbit
Notes: FDA Approval Package
25 mg/kg/day Embryo-foetal development
Result: Maternal NOAEL, Foetal NOAEL
Species: Rat
Notes: FDA Approval Package
45 mg/kg/day Embryo-foetal development
Result: Maternal NOAEL, Foetal NOAEL
Species: Rabbit
Notes: FDA Approval Package
64 mg/kg/day Female Fertility / Early Embryonic Developmen t Result: Negative
Species: Mouse
75 - 225 mg/kg/day Embryo-foetal development
Result: Maternal toxicity; adverse effects on offspring.
Species: Rat
Notes: FDA Approval Package
96 mg/kg/day Embryo-foetal development
Result: Maternal NOAEL, Foetal NOAEL
Species: Mouse
Notes: FDA Approval Package

Specific target organ toxicity - single exposure Not assigned.

Specific target organ toxicity - repeated exposure Not assigned.

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

Further information Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity Not expected to be harmful to aquatic organisms.

Components		Species	Test Results
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)			
Aquatic			
Acute			
Fish	EC50	Fish	> 100 mg/L, 96 hours
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
Microtox	EC50	Microtox	12.5 mg/l, 15 minutes
POLYETHYLENE GLYCOL 400 (CAS 25322-68-3)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	53000 mg/l, 48 hours
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	87000 mg/l, 96 hours
Microtox	EC50	Microtox	100000 mg/l, 15 minutes
SILICON DIOXIDE (CAS 7631-86-9)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	440 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	60 mg/l, 72 hours

Components		Species	Test Results
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 24 hours Static test
Fish	EC50	Common carp (Juvenile Cyprinus carpio)	> 10000 mg/l, 72 hours
		Zebra fish (Adult Brachydanio rerio)	5000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	8700 mg/l, 15 minutes
TITANIUM DIOXIDE (CAS 13463-67-7)			
Aquatic			
Acute			
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-atmospheric)

MAGNESIUM STEARATE	17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE	210 nm

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

MAGNESIUM STEARATE	77 %, 28 days BOD
POLYETHYLENE GLYCOL 400	40.2 - 70 %, 20 Days BOD20

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE	50 %, 13 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

HYDROXYPROPYL METHYL CELLULOSE	-5

Bioconcentration factor (BCF)

HYDROXYPROPYL METHYL CELLULOSE	3.2 Estimated
MAGNESIUM STEARATE	> 9999 Estimated

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE	5.86 Estimated

Mobility in general Not available.

Volatility

Henry's law

HYDROXYPROPYL METHYL CELLULOSE	0 atm m3/mol Estimated

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Observe all local and national regulations when disposing of this product. Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

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 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

One or more components are not listed on TSCA.

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 - No
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. Massachusetts RTK - Substance List

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
SILICON DIOXIDE (CAS 7631-86-9)
TITANIUM DIOXIDE (CAS 13463-67-7)

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

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
SILICON DIOXIDE (CAS 7631-86-9)
TITANIUM DIOXIDE (CAS 13463-67-7)

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

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
SILICON DIOXIDE (CAS 7631-86-9)
TITANIUM DIOXIDE (CAS 13463-67-7)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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

Issue date 08-13-2014

Revision date 08-13-2014

Version # 04

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings
Health: 1
Flammability: 0
Physical hazard: 0

NFPA ratings
Health: 1
Flammability: 0
Instability: 0

References GSK Hazard Determination

Disclaimer 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.

Revision Information
Product and Company Identification: Business Units
Composition / Information on Ingredients: Undisclosed Ingredient Statement
Physical & Chemical Properties:
Regulatory Information: United States
GHS: Classification