



SAFETY DATA SHEET

1. Identification

Product identifier **REQUIP-MODUTAB PROLONGED RELEASE TABLETS**

Other means of identification Not available.

Synonym(s) REQUIP LP * REQUIP XL * REQUIP DEPOT * REQUIP-MODUTAB * REQUIP PROLONGED RELEASE 1 MG TABLETS * REQUIP PROLONGED RELEASE 2 MG TABLETS * REQUIP PROLONGED RELEASE 3 MG TABLETS * REQUIP PROLONGED RELEASE 4 MG TABLETS * REQUIP PROLONGED RELEASE 5 MG TABLETS * REQUIP PROLONGED RELEASE 6 MG TABLETS * REQUIP PROLONGED RELEASE 7 MG TABLETS * REQUIP PROLONGED RELEASE 8 MG TABLETS * REQUIP PROLONGED RELEASE 9 MG TABLETS * REQUIP PROLONGED RELEASE 10 MG TABLETS * REQUIP PROLONGED RELEASE 11 MG TABLETS * REQUIP PROLONGED RELEASE 12 MG TABLETS * ROPINIROLE 3 LAYER TABLETS * ROPINIROLE 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

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	3.0 - 4.0
ROPINIROLE HYDROCHLORIDE	4-[2-DIPROPYLAMINO)ETHYL]-1,3-DIHYDR SKF-101468-A	91374-20-8	0.2 - 2.5
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	<1.0
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 TITANOKSIID	13463-67-7	<1.0
Other components below reportable levels			>90.0

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

4. First-aid measures

Inhalation

In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention immediately.

Skin contact

Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion

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.

Most important symptoms/effects, acute and delayed

The following adverse effects have been noted with therapeutic use of this material: somnolence; dizziness; fainting; incoordination; nausea; abdominal pain; vomiting; constipation; swelling; vertigo; fatigue; hallucinations.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

General information

IF exposed or concerned: Get medical advice/attention. 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 fog. 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

In the event of fire, cool tanks with water spray.

Specific methods

Cool containers exposed to flames with water until well after the fire is out.

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 MSDS.

Methods and materials for containment and cleaning up

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.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Obtain special instructions before use. Avoid contact during pregnancy/while nursing. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the MSDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components

Type

Value

Note

MAGNESIUM STEARATE (CAS 557-04-0)

OHC

1

ROPINIROLE HYDROCHLORIDE (CAS 91374-20-8)

8 HR TWA

20 mcg/m3

OHC

3

REPRODUCTIVE HAZARD

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

Components

Type

Value

Form

TITANIUM DIOXIDE (CAS 13463-67-7)

PEL

15 mg/m3

Total dust.

US. ACGIH Threshold Limit Values

Components

Type

Value

MAGNESIUM STEARATE (CAS 557-04-0)

TWA

10 mg/m3

TITANIUM DIOXIDE (CAS 13463-67-7)

TWA

10 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. 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.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).
Hand protection 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 Not normally needed.
Respiratory protection Wear positive pressure self-contained breathing apparatus (SCBA).
Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations 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 Not available.

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.

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.

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** Harmful if swallowed.
- 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** 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: somnolence; dizziness; fainting; incoordination; nausea; abdominal pain; vomiting; constipation; swelling; anxiety; vertigo; fatigue; hallucinations.

Information on toxicological effects

Acute toxicity Harmful if swallowed.

Components	Species	Test Results
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
POLYVINYLPIRROLIDONE (CAS 9003-39-8)		
Acute		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
ROPINIROLE HYDROCHLORIDE (CAS 91374-20-8)		
Acute		
<i>Oral</i>		
LD50	Mouse	600 mg/kg
	Rat	983 mg/kg
Chronic		
<i>Oral</i>		
LOEL	Human	0.08 mg/kg/day, Inhibition of prolactin secretion.
	Monkey	>= 5 mg/kg/day, 1 years, Inhibition of prolactin secretion.
NOEL	Rat	5 mg/kg/day, 1 years, Inhibition of prolactin secretion.
TITANIUM DIOXIDE (CAS 13463-67-7)		
Acute		
<i>Inhalation</i>		
LC50	Rat	6820 mcg/m3
<i>Oral</i>		
LD50	Rat	> 24 g/kg
Chronic		
<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
Subacute		
<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.

Components	Species	Test Results
<i>Oral</i> NOAEL	Rat	100000 ppm, 14 Day, Dietary study, highest dose tested.
Subchronic <i>Inhalation</i> LOEC	Rat	3.2 - 20 mg/m ³ , 8 min, Accumulation of TiO ₂ 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
ROPINIROLE HYDROCHLORIDE		Acute dermal irritation; OECD 404, P.I.I. = 0.3 Result: Slightly irritating Species: Rabbit
TITANIUM DIOXIDE		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	Direct contact with eyes may cause temporary irritation.	
Eye		
ROPINIROLE HYDROCHLORIDE		OECD 405, Kay and Calandra grade 5; Group mean score 5 (unwashed) Result: Irritant Species: Rabbit
TITANIUM DIOXIDE		OECD 405, Literature data Result: Mild irritant Species: Rabbit
ROPINIROLE HYDROCHLORIDE		Single rabbit (Washed): Group mean score; 11. Result: Irritant Species: Rabbit
Eye / Kay and Calandra class - Intact		
MAGNESIUM STEARATE		4 Recovery Period: 2 days
Respiratory sensitization	Not available.	
Skin sensitization	This product is not expected to cause skin sensitization.	
Sensitization		
TITANIUM DIOXIDE		5 % Optimisation Test, Literature data - Vehicle: petrolatum Result: Negative Species: Guinea pig Test Duration: 48 hour exposure
ROPINIROLE HYDROCHLORIDE		OECD 406, 0 % Response rate. Result: Negative Species: Rabbit
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.	
ROPINIROLE HYDROCHLORIDE		Ames, GLP Result: Negative
TITANIUM DIOXIDE		Ames, Literature data Result: Negative
ROPINIROLE HYDROCHLORIDE		Chromosomal Aberration Assay In Vitro, GLP Result: Negative GreenScreen Result: Negative L5178Y mouse lymphoma thymidine kinase locus assay, GLP Result: Negative

TITANIUM DIOXIDE	Micronucleus Assay in vitro, CHO cells, Literature data Result: Negative
	Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data Result: Positive
ROPINIROLE HYDROCHLORIDE	Micronucleus Assay, GLP Result: Negative
	Species: Mouse
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

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
ROPINIROLE HYDROCHLORIDE	1.5 mg/kg/day Result: NOAEL Species: Rat Test Duration: 2 years
TITANIUM DIOXIDE	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
ROPINIROLE HYDROCHLORIDE	15 - 50 mg/kg/day, Species-specific Result: Positive Species: Rat Organ: testes - leydig cell Test Duration: 2 years
TITANIUM DIOXIDE	25000 - 50000 ppm, Dietary study Result: Negative Species: Mouse
	25000 - 50000 ppm, Dietary study - Literature data. Result: Negative Species: Rat
ROPINIROLE HYDROCHLORIDE	5 - 50 mg/kg/day Species: Mouse Test Duration: 18 months
TITANIUM DIOXIDE	7.2 - 14.8 mg/m3, Literature data Result: Lung tumour Species: Rat Test Duration: 24 months

IARC Monographs. Overall Evaluation of Carcinogenicity

POLYVINYLPIRROLIDONE (CAS 9003-39-8)	3 Not classifiable as to carcinogenicity to humans.
TITANIUM DIOXIDE (CAS 13463-67-7)	2B Possibly carcinogenic to humans.

Reproductive toxicity

Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.

ROPINIROLE HYDROCHLORIDE	120 mg/kg/day Embryo-foetal development Result: foetal digit malformations. Species: Rat
	<= 20 mg/kg/day Embryo-foetal development Result: Foetal NOAEL Species: Rabbit
	>= 60 mg/kg/day Embryo-foetal development, Species-specific Result: foetal toxicity- decreased foetal weight and increased post-implanation loss. Species: Rat
	Fertility Result: Negative Species: Rat
	Pre- and Post-natal development Result: Negative Species: Rat

Specific target organ toxicity - single exposure	Central nervous system.
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	Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity No information is available about the potential of this product to produce adverse environmental effects. Contains a substance which causes risk of hazardous effects to the environment.

Components	Species	Test Results
MAGNESIUM STEARATE (CAS 557-04-0)		
Aquatic		
<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
POLYVINYLPIRROLIDONE (CAS 9003-39-8)		
<i>Acute</i>		
	IC50	Activated sludge > 1000 mg/l, 3 hours, Static test
Aquatic		
<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
ROPINIROLE HYDROCHLORIDE (CAS 91374-20-8)		
Aquatic		
<i>Acute</i>		
Activated Sludge Respiration	IC50	Residential sludge 500 mg/L, 3 hours, OECD 209
Algae	EC50	Green algae (<i>Selenastrum capricornutum</i>) 29.3 mg/L, 72 hours, OECD 201
	NOEC	Green algae (<i>Selenastrum capricornutum</i>) 8.8 mg/L, 72 hours
Crustacea	EC50	Water flea (<i>Daphnia magna</i>) 41.1 mg/L, 48 hours, Static test, OECD 202
	NOEC	Water flea (<i>Daphnia magna</i>) 4.4 mg/L, 48 hours, Static test
Fish	EC50	Bluegill sunfish (Adult <i>Lepomis macrochirus</i>) 11 mg/L, 96 hours, Static test, OECD 203
	NOEC	Bluegill sunfish (Adult <i>Lepomis macrochirus</i>) 3.7 mg/L, 96 hours, Static test
Microtox	EC50	Microtox 362 mg/L, 15 minutes
<i>Chronic</i>		
Crustacea	EC50	Water flea (<i>Ceriodaphnia dubia</i>) 7.7 mg/L, 8 days, 7 day static renewal, EPA 1002
	LOEC	Water flea (<i>Ceriodaphnia dubia</i>) 10 mg/l, 8 days
	NOEC	Water flea (<i>Ceriodaphnia dubia</i>) 3.2 mg/L, 8 days
TITANIUM DIOXIDE (CAS 13463-67-7)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Water flea (<i>Daphnia magna</i>) > 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)

ROPINIROLE HYDROCHLORIDE

433 - 13700 Days Measured

Photolysis

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE 210 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

ROPINIROLE HYDROCHLORIDE 163 Days Measured

Biodegradability

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE 50 %, 13 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

ROPINIROLE HYDROCHLORIDE 2.84 (Measured).

Bioconcentration factor (BCF)

MAGNESIUM STEARATE > 9999 Estimated

Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

ROPINIROLE HYDROCHLORIDE 1.92, pH 7

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE 5.86 Estimated

ROPINIROLE HYDROCHLORIDE 0.74 Calculated, pH 7

Mobility in general

Distribution

Octanol/water distribution coefficient log DOW

ROPINIROLE HYDROCHLORIDE 2.33, pH 8.4

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. This material and its container must be disposed of as hazardous waste. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international 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).

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)

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

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

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.

Food and Drug Administration (FDA) Not regulated.

US state regulations**US. Massachusetts RTK - Substance List**

TITANIUM DIOXIDE (CAS 13463-67-7)

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

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

Issue date 10-31-2013

Revision date 10-31-2013

Version #	11
Further information	This material has not been assessed for HMIS or NFPA ratings.
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: Ingredients Physical & Chemical Properties: Transport Information: Agency Name, Packaging Type, and Transport Mode Selection Regulatory Information: United States