SAFETY DATA SHEET

1. Identification

Product identifier **SOLPADEINA MAX / PANADOL ULTRA**

Other means of identification Not available.

Synonym(s) ALG815 * CODEINE AND PARACETAMOL, 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	%
PARACETAMOL	ACETAMIDE, N-(4-HYDROXYPHENYL)- N-(4-HYDROXYPHENYL) ACETAMIDE ACETANILIDE, 4'-HYDROXY- 4'-HYDROXYACETANILIDE 4-HYDROXYACETANILIDE PANADOL PARACETAMOL TEMPRA TYLENOL PARA-ACETAMIDOPHENOL 4-ACETAMIDOPHENOL 4-ACETAMINOPHENOL PARA-(ACETYLAMINO)PHENOL PARA-HYDROXYACETANILIDE RHODAPAP DC90 (PARACETAMOL CRYSTAL FINE)	103-90-2	74.8

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
TALC	TALCUM, NON-ASBESTOS FORM AGALITE ASBESTINE TALCUM TALC FINNTALC EMTAL SOAPSTONE STEATITE NYTAL HYDROUS MAGNESIUM SILICATE MISTRON BEAVER WHITE FRENCH CHALK MUSSOLINITE STEAWHITE TALCRON- MONTANA TALC H2Mg3O12Si4 OHS22400 RTECS WW2710000	14807-96-6	2.2
CODEINE PHOSPHATE HEMIHYDRATE	MORPHINAN-6-OL, 7,8-DIDEHYDRO-4,5-EPOXY-3-METHOXY-1 (5.ALPHA.,6.ALPHA.)-, PHOSPHATE (1:1) (SALT), HEMIHYDRATE (5.ALPHA.,6.ALPHA.)-7,8-DIDEHYDRO-4,5-E MORPHINAN-6-OL PHOSPHATE (1:1) (SALT), HEMIHYDRATE AH5317D	41444-62-6	2
POLYVINYLPYRROLIDONE	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	0.7
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	0.3

Hazardous components Chemical name	Common name and synonyms	CAS number	%
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 TITAANOKSIID	13463-67-7	0.131506849315
Other components below reportable levels			19.868493150685

*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. Remove and isolate 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
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.

Most important symptoms/effects, acute and delayed
May cause allergic respiratory reaction. May cause allergic skin reaction. Direct contact with eyes may cause temporary irritation. The following adverse effects have been noted with therapeutic use of this material: symptoms similar to alcohol intoxication; dizziness; drowsiness; constipation; dry mouth; sweating; itching; urine retention.

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 local poison control information centre.

General information
The need for pre-placement and periodic health surveillance must be determined by risk assessment. Following assessment, if the risk of exposure is considered significant then exposed individuals should receive health surveillance focused on detecting respiratory symptoms and including respiratory function testing.
In the event of overexposure, individuals should receive post exposure health surveillance focused on detecting respiratory conditions and other allergy symptoms.

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
Move containers from fire area if you can do so without risk.

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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. 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. Do not handle until all safety precautions have been read and understood. Do not taste or swallow. Avoid contact with skin. 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. Avoid release to the environment. Do not empty into drains.

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 in a well-ventilated place. Store away from incompatible materials (see Section 10 of the MSDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
CODEINE PHOSPHATE HEMIHYDRATE (CAS 41444-62-6)	8 HR TWA	200 mcg/m3	
	OHC	2	SKIN
		2	SKIN SENSITISER
		2	REPRODUCTIVE HAZARD
		2	RESPIRATORY SENSITISER
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1	
PARACETAMOL (CAS 103-90-2)	8 HR TWA	4000 mcg/m3	
	OHC	1	

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. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value	Form
TALC (CAS 14807-96-6)	TWA	0.3 mg/m3	Total dust.
		0.1 mg/m3	Respirable.
		20 millions of particle	
		2.4 millions of particle	Respirable.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	
TALC (CAS 14807-96-6)	TWA	2 mg/m3	Respirable fraction.
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	10 mg/m3	

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
TALC (CAS 14807-96-6)	TWA	2 mg/m3	Respirable.

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 Eye wash fountain is recommended. Wear approved safety glasses with side shields if eye contact is possible.

Hand protection Wear 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	Normal work clothing (long sleeved shirts and long pants) is recommended.
Respiratory protection	Not available.
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice. New or expectant mothers are at greater risk if exposed to the active ingredient which is readily absorbed through the skin. They should not handle unpackaged product. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices.

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	Alkaline metals. Peroxides. Acids. 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	Harmful if swallowed.
Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin contact	May cause an allergic skin reaction.

Eye contact	Direct contact with eyes may cause temporary irritation.
Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation. The following adverse effects have been noted with therapeutic use of this material: symptoms similar to alcohol intoxication; dizziness; drowsiness; nausea; vomiting; constipation; dry mouth; sweating; itching; urine retention.

Information on toxicological effects

Acute toxicity Harmful if swallowed. May cause allergic skin reaction.

Components	Species	Test Results
CODEINE PHOSPHATE HEMIHYDRATE (CAS 41444-62-6)		
Acute		
Oral		
LD50	Rat	85 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
PARACETAMOL (CAS 103-90-2)		
Acute		
Oral		
LD50	Rat	1944 mg/kg
TD	Human	>= 150 mg/kg
Subacute		
Oral		
NOAEL	Rat	12500 ppm, 14 Day, dietary, continuous
Subchronic		
Oral		
NOAEL	Rat	6200 ppm, 13 weeks, dietary, continuous
TD	Rat	>= 12500 ppm, 13 weeks, dietary, continuous
Other		
LOAEL	Mouse	130 ppm, 61 weeks, dietary, continuous
NOAEL	Mouse	3200 ppm, 13 weeks, dietary, continuous
		0.3 %, 41 weeks, dietary, continuous
TD	Mouse	6100 ppm, 13 weeks, dietary, continuous
		1.25 %, 41 weeks, dietary, continuous
POLYVINYLPYRROLIDONE (CAS 9003-39-8)		
Acute		
Oral		
LD50	Rat	> 5000 mg/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 Prolonged skin contact may cause temporary irritation.

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
PARACETAMOL	OECD 404, Literature data Result: Slight irritant Species: Rabbit

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye

PARACETAMOL	OECD 405 Result: Slight irritant Species: Rabbit
TITANIUM DIOXIDE	OECD 405, Literature data Result: Mild irritant Species: Rabbit

Eye / Initial pain reaction score

PARACETAMOL	Literature data

Eye / Kay and Calandra class - Intact

MAGNESIUM STEARATE	4 Recovery Period: 2 days

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

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 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.

PARACETAMOL	Ames, Literature data Result: Negative
TITANIUM DIOXIDE	Ames, Literature data Result: Negative
PARACETAMOL	Chromosomal Aberration Assay In Vitro, Literature data Result: Positive

PARACETAMOL	HPRT gene mutation in human lymphocytes, Literature data Result: Negative In vivo Micronucleus, Literature data Result: Negative Species: Mouse
TITANIUM DIOXIDE	Micronucleus Assay in vitro, CHO cells, Literature data Result: Negative Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data Result: Positive 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 is listed as a carcinogen by external agencies. Talc is listed as a carcinogen by external agencies. 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 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
PARACETAMOL	Literature data Result: Equivocal. Increase in ademomas at toxic dose. Species: Mouse Literature data Result: Equivocal. Liver and bladder neoplasms at toxic doses. Species: Rat Literature data Result: Negative Species: Mouse Literature data Result: Negative Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity

PARACETAMOL (CAS 103-90-2)	3 Not classifiable as to carcinogenicity to humans.
POLYVINYLPYRROLIDONE (CAS 9003-39-8)	3 Not classifiable as to carcinogenicity to humans.
TALC (CAS 14807-96-6)	2B Possibly carcinogenic to humans. 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.

PARACETAMOL	250 mg/kg/day Embryofetal Development, Literature data Result: Foetal NOAEL Species: Rat 387 mg/kg/day Embryofetal Development, Literature data Result: Negative Species: Mouse 750 mg/kg/day Embryofetal Development, Literature data Result: decrease in foetal weght, minor skeletal abnormalities. Species: Rat

PARACETAMOL	<= 1400 mg/kg/day Pre- and Post-natal development, Literature data Result: reduced weight gain during nursing. Species: Rat Epidemiology, Literature data Result: No clear association with therapeutic use. Species: Human

Specific target organ toxicity - single exposure Causes damage to organs. Liver.

PARACETAMOL	Species: Human Organ: Liver

Specific target organ toxicity - repeated exposure May cause damage to organs through prolonged or repeated exposure. Liver.

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

Chronic effects Prolonged inhalation may be harmful. Prolonged exposure may cause chronic effects.

Further information Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity Harmful to aquatic life. Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test Results
CODEINE PHOSPHATE HEMIHYDRATE (CAS 41444-62-6)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia pulex)	85.05 mg/l, 24 hours, Nominal
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
PARACETAMOL (CAS 103-90-2)			
Aquatic			
Acute			
Algae	EC50	Green algae (Scenedesmus subspicatus)	134 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	50 mg/l, 48 hours, Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	814 mg/l, 96 hours, Flow-through test
POLYVINYLPYRROLIDONE (CAS 9003-39-8)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours, Static test
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	84 mg/l, 48 hours, Static test
	NOEC	Water flea (Daphnia magna)	32 mg/l, 48 hours, Static test
TALC (CAS 14807-96-6)			
Aquatic			
Acute			
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 100 g/l, 24 hours, Static renewal test
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-soil)

MAGNESIUM STEARATE	50 %, 13 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

PARACETAMOL	0.36
CODEINE PHOSPHATE HEMIHYDRATE	0.978 (Calculated).

Bioconcentration factor (BCF)

MAGNESIUM STEARATE	> 9999 Estimated

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE	5.86 Estimated

Mobility in general

Volatility

Henry's law

PARACETAMOL	0 atm m^3/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. 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

TALC (CAS 14807-96-6)
TITANIUM DIOXIDE (CAS 13463-67-7)

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

TALC (CAS 14807-96-6)
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)	Yes
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	08-16-2013
Revision date	08-16-2013
Version #	12
Further information	This material has not been assessed for HMIS or NFPA ratings. HMIS® is a registered trade and service mark of the NPCA.
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: Multiple Properties Toxicological Information: Transport Information: Agency Name, Packaging Type, and Transport Mode Selection