SAFETY DATA SHEET

1. Identification

Product identifier **MEKINIST TABLETS**

Other means of identification

Synonyms TRAMETINIB TABLETS * TRAMETINIB AQUEOUS FILM COATED TABLETS * TRAMETINIB AQUEOUS FILM COATED TABLETS 0.25 MG - 2.0MG * GSK1120212B AQUEOUS FILM COATED TABLETS 0.25 MG - 2.0MG * TRAMETINIB, FORMULATED PRODUCT * GSK1120212B, 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	%
TRAMETINIB	GSK1120212B * N-[3-[3-CYCLOPROPYL-5-[(2-FLUORO-4-IODOPHENYL)AMINO]-6,8-DIMETHYL-2,4,7-TRIOXO-3,4,6,7-TETRAHYDROPYRIDO[4,3-D]PYRIMIDIN-1(2H)-YL]PHENYL]ACETAMIDE, COMPOUND WITH DIMETHYLSULFOXIDE (1:1) * JTP-74057	108-78-1	0.2 - 2.0
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT * MAGNESIUM DISTEARATE * DIBASIC MAGNESIUM STEARATE * MAGNESIUM DISTEARATE, PURE	557-04-0	<1.0

Chemical name	Common name and synonyms	CAS number	%
TITANIUM DIOXIDE	TITANIUM OXIDE * TITANIUM(IV) OXIDE * TITANIUM PEROXIDE (TiO2) * PIGMENT WHITE 6	13463-67-7	<1.0
DODECYL SODIUM SULFATE	DODECYL SULFATE, SODIUM SALT * SODIUM LAURYL SULPHATE * LAURYL SULFATE SODIUM SALT	151-21-3	<0.1
Other components below reportable levels			>95.0

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

4. First-aid measures

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

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
May cause allergic skin reaction.
The following adverse effects have been noted with therapeutic use of this material: bone marrow toxicity; gastrointestinal distress; cardiovascular effects; symptoms of hypersensitivity (such as skin rash, hives, itching); fatigue; anaemia; skin changes. Additional effects of overexposure may occur.

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 centre.

General information
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

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
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 protective equipment and clothing during clean-up. 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 breaking or crushing tablets. Avoid breathing dusts from this material. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact with eyes, skin, and clothing. Avoid contact during pregnancy/while nursing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices. 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. Refrigeration recommended. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
DODECYL SODIUM SULFATE (CAS 151-21-3)	OHC	2	
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1	
TRAMETINIB (CAS 108-78-1)	8 HR TWA	2 mcg/m3	
	OHC	4	SKIN SENSITISER
		4	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

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.

Skin protection

Hand protection

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

Other

Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection

No personal respiratory protective equipment normally required. 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

For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. Consider control procedures for maintenance, cleaning and emergencies. New or expectant mothers might be at greater risk from overexposure. 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)	
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	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	Hazardous polymerization does not occur.
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

Inhalation	Health injuries are not known or expected under normal use. Do not breathe dust/fume/gas/mist/vapors/spray.
Skin contact	Health injuries are not known or expected under normal use. May cause an allergic skin reaction.
Eye contact	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
Ingestion	Health injuries are not known or expected under normal use. May be harmful if swallowed.
Symptoms related to the physical, chemical and toxicological characteristics	May cause an allergic skin reaction. The following adverse effects have been noted with therapeutic use of this material: bone marrow toxicity; gastrointestinal distress; cardiovascular effects; symptoms of hypersensitivity (such as skin rash, hives, itching); fatigue; anaemia; skin changes. Additional effects of overexposure may occur.

Information on toxicological effects

Acute toxicity	Health injuries are not known or expected under normal use. May be harmful if swallowed.

Components	Species	Test Results
DODECYL SODIUM SULFATE (CAS 151-21-3)		
Acute		
Oral		
LD50	Rat	1288 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	> 2000 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
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.
TRAMETINIB (CAS 108-78-1)		
Subacute		
Oral		
LD	Rat	1 mg/kg/day, 14 days
Subchronic		
Oral		
NOAEL	Dog	< 0.03 mg/kg/day, 13 weeks Gastro-intestinal lesions, bone marrow
	Rat	< 0.02 mg/kg/day, 13 weeks Stomach, Reduced corpora lutea

* 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. Prolonged skin contact may cause temporary irritation.

Irritation Corrosion - Skin

TITANIUM DIOXIDE	0, Literature data Result: Non-irritant Species: Guinea pig 0, Literature data Result: Non-irritant Species: Human Acute dermal irritation; OECD 404, Literature data Result: Non-irritant Species: Rabbit
TRAMETINIB	Reconstituted Human Epidermis (RHE) Result: Negative

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
TRAMETINIB	Reconstituted Human Corneal Epithelium (HCE) Result: Negative

Eye / Kay and Calandra class - Intact

MAGNESIUM STEARATE	4 Recovery Period: 2 days

Respiratory or skin sensitization

Respiratory sensitization Not available.

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
TRAMETINIB	OECD 429 / Local Lymph Node Assay, Maximum concentration = 1%; vehicle = acetone:olive oil 4:1; SI = 6.4 Result: Positive Species: Mouse Occupational exposure Result: Positive (limited number of reported cases) Species: Human
TITANIUM DIOXIDE	Patch test, Literature data Result: Negative Species: Human

Germ cell mutagenicity Health injuries are not known or expected under normal use.

Mutagenicity

TRAMETINIB	Ames Assay, GLP assay Result: Negative
TITANIUM DIOXIDE	Ames, Literature data Result: Negative Micronucleus Assay in vitro, CHO cells, Literature data Result: Negative Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data Result: Positive
TRAMETINIB	Micronucleus Assay, GLP assay; maximum dose = 2 mg/kg (oral MTD) Result: Negative Species: Rat Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay Result: Negative
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 Health injuries are not known or expected under normal use. Contains a material (titanium dioxide) classified as a carcinogen by external agencies. Carcinogenic activity was seen in inhalation studies using laboratory animals. High concentrations or doses administered over an extended period of time were required to produce adverse effects.

TITANIUM DIOXIDE	0.5 mg/m3, Literature data Result: Negative Species: Rat Test Duration: 24 months 0.72 - 14.8 mg/m3, Literature data Result: Negative Species: Mouse 10 - 250 mg/m3, Dietary study - Literature data. Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration. Species: Rat Test Duration: 24 months 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
TRAMETINIB	SAR / QSAR, DEREK, Lhasa, UK Result: Negative

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 The ingredient trametinib has caused adverse effects on the development of unborn offspring in animal studies.

Reproductivity

TRAMETINIB	Embryo-foetal development - Oral Result: Foetal NOAEL = 0.016 mg/kg/day; decreased foetal weight with doses >/= 0.031 mg/kg/day; no other foetal adverse effects or malformations Species: Rat Embryo-foetal development - Oral Result: Foetal NOAEL not identified; decreased foetal weight and ossification delays with doses >/= 0.039 mg/kg/day; maternal toxicity with dose = 0.039 mg/kg/day Species: Rabbit Fertility, Female Result: Decreased corpora lutea and increased ovarian cysts (>/= 0.016 mg/kg/day, 13 week study) Species: Rat Fertility, Male, No effects on male reproductive organs (rats, dogs) in repeat dose studies to 13 weeks Result: Negative Species: Rat

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure Causes damage to organs through prolonged or repeated exposure.

Aspiration hazard Not available.

Chronic effects Prolonged exposure may cause chronic effects. Prolonged inhalation may be harmful. Causes damage to organs through prolonged or repeated exposure.

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. The product contains a substance which may cause long-term adverse effects in the environment.

Components		Species	Test Results
DODECYL SODIUM SULFATE (CAS 151-21-3)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	5.4 mg/l, 48 hours Static test
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	4.6 mg/l, 96 hours Flow-through test
Chronic			
Algae	NOEC	Green algae (Desmodesmus subspicatus)	30 mg/l, 72 hours
Crustacea	NOEC	Ceriodaphnia dubia	0.88 mg/l, 7 days Flow-though Test
Fish	NOEC	Fathead minnow (Pimephales promelas)	3.8 mg/l, 28 days Flow-through test
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
TITANIUM DIOXIDE (CAS 13463-67-7)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours Static test
TRAMETINIB (CAS 108-78-1)			
Aquatic			
Acute			
Algae	EC50	Green algae (Pseudokirchnereilla subcapitata)	> 0.045 mg/l, 72 hours Nominal, OECD 201
	NOEC	Green algae (Pseudokirchnereilla subcapitata)	0.045 mg/l, 72 hours
Chronic			
Crustacea	LOEC	Water flea (Daphnia magna)	> 0.045 mg/l, 21 days semi-static test , OECD 211
	NOEC	Water flea (Daphnia magna)	0.0146 mg/l, 21 days
Fish	Growth test LOEC	Fathead minnow (Juvenile Pimephales promelas)	0.0146 mg/l, 28 days Nominal, OECD 210
	Growth test NOEC	Fathead minnow (Juvenile Pimephales promelas)	0.0045 mg/l, 28 days

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

Persistence and degradability No data is available on the degradability of this product.

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

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE	50 %, 13 days

Bioaccumulative potential No data available.

Partition coefficient n-octanol / water (log Kow)

DODECYL SODIUM SULFATE	1.6
TRAMETINIB	4.04 (measured)

Bioconcentration factor (BCF)

MAGNESIUM STEARATE	> 9999 Estimated

Mobility in soil Not available.

Adsorption

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE	5.86 Estimated

Mobility in general Not available.

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

UN number UN3077

UN proper shipping name Environmentally hazardous substances, solid, n.o.s. (TRAMETINIB TABLETS)

Transport hazard class(es)

Class 9

Subsidiary risk -

Label(s) 9

Packing group III

Special precautions for user May be able to ship as an Excepted or Limited Quantity. Review all HazMat Table packaging exceptions and instructions to identify options.
Consumer Commodity, ORM-D may apply.See 173.155.

Special provisions 8, 146, 335, A112, B54, IB8, IP3, N20, T1, TP33

Packaging exceptions 155

Packaging non bulk 213

Packaging bulk 240

May be able to ship as an Excepted or Limited Quantity. Review all HazMat Table packaging exceptions and instructions to identify options.
ID 8000, Consumer Commodity, may apply. See Packing Instruction Y963.

IATA

UN number UN3077

UN proper shipping name Environmentally hazardous substance, solid, n.o.s. (TRAMETINIB TABLETS)

Transport hazard class(es) 9

Subsidiary class(es) -

Packaging group III

Labels required Not available.

Environmental hazards No.

ERG Code 9L

Special precautions for user May be able to ship as an Excepted or Limited Quantity. Review all HazMat Table packaging exceptions and instructions to identify options.
ID 8000, Consumer Commodity, may apply. See Packing Instruction Y963.

Other information

Cargo aircraft only Allowed.

Passenger & cargo Allowed.

IMDG

UN number UN3077

UN proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (TRAMETINIB TABLETS)

Transport hazard class(es)

Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	
Marine pollutant	No.
EmS	F-A, S-F
Special precautions for user	May be able to ship as an Excepted or Limited Quantity. Review all HazMat Table packaging exceptions and instructions to identify options. May be exempt from IMDG regulations.See SP 335.
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.

DOT; IATA; IMDG

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
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

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

Not listed.

US. Massachusetts RTK - Substance List

TITANIUM DIOXIDE (CAS 13463-67-7)

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

TITANIUM DIOXIDE (CAS 13463-67-7)

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

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)	Yes
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	10-22-2014
Revision date	10-22-2014
Version #	10
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 2 Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 2 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	This document has undergone significant changes and should be reviewed in its entirety.