



SAFETY DATA SHEET

1. Identification

Product identifier	MEKINIST TABLETS
Other means of identification	Not available.
Synonym(s)	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

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
TRAMETINIB	GSK1120212B N-[3-[3-CYCLOPROPYL-5-[(2-FLUORO-4-IO TRIOXO-3,4,6,7-TETRAHYDROPYRIDO[4,3- COMPOUND WITH DIMETHYLSULFOXIDE (1:1) JTP-74057	108-78-1	0.2 - 2.0
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

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
TITANIUM DIOXIDE	ANATASE BROOKITE RUTILE TITANIUM OXIDE TITANIUM DIOXIDE (TiO ₂) C.I. PIGMENT WHITE 6 C.I. 77891 TITANIUM(IV) OXIDE TITANIUM(4+) OXIDE TITANIUM PEROXIDE (TiO ₂) TITANIA (TiO ₂) PIGMENT WHITE 6 TITANIA KRONOS TITANIC OXIDE O2Ti OHS23510 RTECS XR2275000 DIOXIDO DE TITANIO TITANOKSIID	13463-67-7	<1.0
DODECYL SODIUM SULFATE	SODIUM DOCECYL SULFATE SODIUM N-DODECYL SULFATE SODIUM DODECYL SULPHATE DODECYL SULFATE, SODIUM SALT SODIUM LAURYL SULPHATE SODIUM MONOLAURYL SULFATE N-DODECYL SULFATE SODIUM LAURYL SODIUM SULFATE LAURYL SULFATE SODIUM LAURYL SULFATE SODIUM SALT MONODODECYL SODIUM SULFATE SODIUM DODECYLSULFATE SULFURIC ACID, MONODODECYL ESTER, SODIUM SALT SODIUM MONODODECYL SULFATE SDS SLS C12H25NaO4S OHS08485 RTECS WT1050000 SULFURIC ACID MONODODECYL ESTER SODIUM SALT (SODIUM LAURYL SULFATE) N-ALKYL(C8-C20)SULFATE, NATRIUMSALZ	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	If not breathing, give artificial respiration. If breathing is difficult, trained personnel should give oxygen. Get medical attention immediately.
Skin contact	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. If skin irritation or rash occurs: Get medical advice/attention. For minor skin contact, avoid spreading material on unaffected skin.
Eye contact	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Get medical attention if irritation develops and persists.
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	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	Provide general supportive measures and treat symptomatically.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. IF exposed or concerned: Get medical advice/attention. Wash contaminated clothing before reuse.

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. 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 MSDS.
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	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. 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 away from incompatible materials (see Section 10 of the MSDS).

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

US. AIHA Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
TRAMETINIB (CAS 108-78-1)	TWA	5 mg/m3	Respirable particles.
		10 mg/m3	Inhalable particles.

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. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them. Open handling is not recommended. Consider segregating operations, use of enclosures and sealed transfer systems.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Wear approved safety glasses with side shields or cover goggles if eye contact is possible.
Hand protection	Wear protective gloves. The selection of gloves for a specific activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Glove selection must take into account any solvents and other hazards present. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided. Care must be exercised if insufficient data are available and further guidance should be sought from your local EHS department.
Other	Wear appropriate chemical resistant clothing.
Respiratory protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. If respiratory protective equipment (RPE) is used, the type of RPE will depend upon air concentrations present, required protection factor as well as hazards, physical properties and warning properties of substances present.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	When using, do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace. Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Consider control procedures for maintenance, cleaning and emergencies. Wear appropriate clothing to avoid skin contact. An eye wash station should be available. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. Entry to the working area should be controlled. Doors with interlocks may be needed for materials airlocks and locker rooms. Only equipment and supplies necessary for job activities should be taken into working area. 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)	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

Ingestion	May be harmful if swallowed.
Inhalation	Not available.
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 The following adverse effects have been noted with therapeutic use of this material: gastrointestinal distress; cardiovascular effects; bone marrow toxicity; symptoms of hypersensitivity (such as skin rash, hives, itching); fatigue; anaemia; skin changes.

Information on toxicological effects

Acute toxicity May be harmful if swallowed.

Components	Species	Test Results
DODECYL SODIUM SULFATE (CAS 151-21-3)		
Acute		
<i>Oral</i>		
LD50	Rat	1288 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
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.

Components	Species	Test Results
NOAEC	Guinea pig	26 mg/m ³ , 3 weeks, No evidence of significant inflammation in respiratory tract.
<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.
TRAMETINIB (CAS 108-78-1)		
Subacute <i>Oral</i> LD	Rat	1 mg/kg/day, 14 days
Subchronic <i>Oral</i> 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 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

Reconstituted Human Epidermis (RHE)

Result: Negative

TRAMETINIB

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

MAGNESIUM STEARATE

0

Serious eye damage/eye irritation 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 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

Sensitization		
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.	
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.
TRAMETINIB (CAS 108-78-1)		3 Not classifiable as to carcinogenicity to humans.
Reproductive toxicity	Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. Suspected of damaging fertility or the unborn child.	
TRAMETINIB		Embryo-foetal development - Oral Result: Foetal NOAEL = 0.016 mg/kg/day; decreased foetal weight with doses \geq 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 \geq 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	Not available.
Specific target organ toxicity - repeated exposure	Causes damage to organs through prolonged or repeated exposure.
Aspiration hazard	Not available.
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
MAGNESIUM STEARATE (CAS 557-04-0)		
Aquatic		
<i>Acute</i>		
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)
		130 mg/l, 96 hours
Microtox	EC50	Microtox
		12.5 mg/l, 15 minutes
TITANIUM DIOXIDE (CAS 13463-67-7)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna)
		> 1000 mg/l, 48 hours, Static test
TRAMETINIB (CAS 108-78-1)		
Aquatic		
<i>Acute</i>		
Algae	EC50	Green algae (Pseudokirchnerella subcapitata)
		> 0.045 mg/l, 72 hours, Nominal, OECD 201
	NOEC	Green algae (Pseudokirchnerella subcapitata)
		0.045 mg/l, 72 hours
<i>Chronic</i>		
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	Fathead minnow (Juvenile Pimephales promelas)
	LOEC	
		0.0146 mg/l, 28 days, Nominal, OECD 210
	Growth test	Fathead minnow (Juvenile Pimephales promelas)
	NOEC	
		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-soil)

MAGNESIUM STEARATE 50 %, 13 days

Bioaccumulative potential Not 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) 9
Subsidiary class(es) Not available.
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.
Labels required 9
Special provisions 8, 146, 335, A112, B54, IB8, IP3, N20, T1, TP33
Packaging exceptions 155
Packaging non bulk 213
Packaging bulk 240
Qty limits cargo No limit
Qty limits passenger No limit

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.
ERG Code 9L
Passenger & cargo Allowed.
Additional Information:
Packaging Instruction 956
Pkg Inst cargo only 956
Pkg Inst passenger & cargo Y956
SP see 44 A97,A158,A179
Max net qty pkg 400 kg
Max net qty pkg cargo only 400 kg
Max net qty pkg LQ 30 kg G

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.

IMDG

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
Environmental hazards	
Marine pollutant	No
Labels required	Not available.
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.

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

NFPA ratings
 Health: 1
 Flammability: 1
 Instability: 0

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

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)
TRAMETINIB (CAS 108-78-1)

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

TITANIUM DIOXIDE (CAS 13463-67-7)
TRAMETINIB (CAS 108-78-1)

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)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
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	12-12-2013
Revision date	12-12-2013
Version #	09
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 1* Flammability: 1 Physical hazard: 0
NFPA ratings	Health: 1 Flammability: 1 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: Synonyms Composition / Information on Ingredients: Undisclosed Ingredient Statement Toxicological information: Carcinogenicity Ecological Information: Ecotoxicity Ecological information: Ecotoxicity Ecological information: Mobility in soil Ecological information: Mobility in general Transport Information: Proper Shipping Name/Packing Group Other information, including date of preparation or last revision: Further information