



SAFETY DATA SHEET

1. Identification

Product identifier

TAFINLAR CAPSULES AND PLACEBO

Other means of identification

Synonyms

TAFINLAR CAPSULES 50 MG * TAFINLAR CAPSULES 75 MG * DABRAFENIB CAPSULES * GSK2118436B CAPSULES * PLACEBO CAPSULES * DABRAFENIB, FORMULATED PRODUCT

Recommended use

Medicinal Product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions

No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249

Email Address: msds@gsk.com
Website: www.gsk.com

EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES:
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
MICROCRYSTALLINE CELLULOSE	AVICEL PH MICROCRYSTALLINE CELLULOSE ALPHA-CELLULOSE AVICEL PH101 AVICEL PH102 AVICEL PH103 AVICEL PH105 AVICEL PH112 AVICEL PH200 CELLULOSE (8CI9CI) CELLULOSE CRYSTALLINE CELLULOSE, FOOD GRADE CRYSTALLINE CELLULOSE	9004-34-6	65.8
PREGELATINIZED STARCH		9005-25-8	0 - 99.5

Chemical name	Common name and synonyms	CAS number	%
DABRAFENIB MESYLATE	GSK2118436B N-{3-[5-(2-AMINO-4-PYRIMIDINYL)-2-(1,1-DIMETHYLETHYL)-1,3-THIAZOL-4-YL]-2-FLUOROPHENYL}-2,6-DIFLUOROBENZENESULFONAMIDE, METHANESULFONATE, (1:1)	1195768-06-9	0 - 35
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE	557-04-0	< 1
SILICON DIOXIDE COLLOIDAL		7631-86-9	0.25

*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	Prolonged exposure may cause chronic effects.
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. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
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.
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. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	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. Prevent further leakage or spillage if safe to do so. Inform appropriate managerial or supervisory personnel of all environmental releases.

7. Handling and storage

Precautions for safe handling	Avoid prolonged exposure. Use personal protective equipment as required. Avoid release to the environment.
--------------------------------------	--

Conditions for safe storage, including any incompatibilities

Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
DABRAFENIB MESYLATE (CAS 1195768-06-9)	8 HR TWA	20 mcg/m3	REPRODUCTIVE HAZARD, CARCINOGEN
	OHC	3	REPRODUCTIVE HAZARD, CARCINOGEN

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

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
PREGELATINIZED STARCH (CAS 9005-25-8)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

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

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

US. ACGIH Threshold Limit Values

Components	Type	Value
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3
PREGELATINIZED STARCH (CAS 9005-25-8)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total
PREGELATINIZED STARCH (CAS 9005-25-8)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total
SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)	TWA	6 mg/m3	

Biological limit values

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

Appropriate engineering controls

General ventilation normally adequate. 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

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. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.
	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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. An occupational/industrial hygiene monitoring method has been developed for this material.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Capsule.
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. Heat, flames and sparks.
Incompatible materials	Strong oxidizing agents. Fluorine.

Hazardous decomposition products None known. Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard. Inhalation of dusts may cause respiratory irritation.

Skin contact Health injuries are not known or expected under normal use. May be irritating to the skin.

Eye contact Health injuries are not known or expected under normal use.

Ingestion Health injuries are not known or expected under normal use. May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics Prolonged exposure may cause chronic effects.

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
DABRAFENIB MESYLATE (CAS 1195768-06-9)		
Acute		
Oral		
LD	Rat	> 1000 mg/kg Micronucleus study
Subchronic		
Oral		
LD	Rat	> 400 mg/kg/day 13 week study
NOAEL	Rat	< 20 mg/kg/day 13 week study
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 2000 mg/kg

* 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.

Corrosivity

DABRAFENIB MESYLATE Reconstituted Human Epidermis (RHE)
Result: Negative; not considered a significant irritant;
GSK2118436A (free base) tested

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

DABRAFENIB MESYLATE Reconstituted Human Corneal Epithelium (HCE)
Result: Negative; not likely to be a severe irritant;
GSK2118436A (free base) tested

Eye / Kay and Calandra class - Intact

MAGNESIUM STEARATE 4
Recovery Period: 2 days

Respiratory or skin sensitization

Respiratory sensitization Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin sensitization	Health injuries are not known or expected under normal use.	
Sensitization		
DABRAFENIB MESYLATE		Local lymph node assay, Maximum test concentration 50%; vehicle DMF; GSK2118436A tested Result: Negative Species: Mouse SAR / QSAR Result: Negative
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic. Health injuries are not known or expected under normal use.	
Mutagenicity		
DABRAFENIB MESYLATE		Ames Assay, GLP assay; GSK2118436A (free base) tested Result: Negative Ames Assay, GLP assay; GSK2118436B tested Result: Negative Micronucleus Assay, GLP assay; tested to MTD of 1000 mg/kg (oral); GSK2118436A (free base) tested Result: Negative Species: Rat Mouse Lymphoma Cell (L5178Y) Assay, GLP assay; GSK2118436A (free base) tested Result: Negative SAR / QSAR, DEREK, Lhasa, UK Result: Negative
Carcinogenicity	Contains a material (dabrafenib) classified as a carcinogen by external agencies. High concentrations or doses administered over an extended period of time were required to produce adverse effects.	
DABRAFENIB MESYLATE		Clinical observation, In cancer patients ingestion of GSK2118436, like other BRAF inhibitors, leads to appearance of squamous cell skin carcinoma. SAR / QSAR Result: Negative
IARC Monographs. Overall Evaluation of Carcinogenicity		
SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)		3 Not classifiable as to carcinogenicity to humans.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)		
Not listed.		
Reproductive toxicity	Contains components which have been classified as: Suspected of damaging fertility or the unborn child.	
Reproductivity		
DABRAFENIB MESYLATE		Female Fertility / Early Embryonic & Embryo-foetal Development Result: Maternal toxicity and decreased corpora lutea, no other fertility effects; foetal lethality, cardiac and thymic defects plus foetal adverse effects noted at lower doses; dose = 300 mg/kg/day; GSK2118436A (free base) tested Species: Rat Female Fertility / Early Embryonic & Embryo-foetal Development Result: Maternal toxicity, no fertility effects; delayed foetal skeletal development and reduced foetal weight; dose >/= 20 mg/kg/day; GSK2118436A (free base) tested Species: Rat
Specific target organ toxicity - single exposure	Not assigned.	
Specific target organ toxicity - repeated exposure	May cause damage to organs through prolonged or repeated exposure.	
Aspiration hazard	Not likely, due to the form of the product.	
Chronic effects	Prolonged inhalation may be harmful. May cause damage to organs through prolonged or repeated exposure.	
Further information	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.	
DABRAFENIB MESYLATE		3T3 Cell / Neutral Red Uptake Assay, Potential phototoxicity Result: Positive

12. Ecological information

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

Components		Species	Test Results
DABRAFENIB MESYLATE (CAS 1195768-06-9)			
Aquatic			
<i>Acute</i>			
Activated Sludge Respiration	IC50	Residential sludge	> 370.3 mg/l, 3 hours OECD 209
	NOEC	Residential sludge	370.3 mg/l, 3 hours
Algae	EC50	Green algae (Pseudokirchnerella subcapitata)	0.33 mg/l, 72 hours Measured, OECD 202
	NOEC	Green algae (Pseudokirchnerella subcapitata)	0.26 mg/l, 72 hours
<i>Chronic</i>			
Crustacea	LOEC	Water flea (Daphnia magna)	> 0.12 mg/l, 21 days semi-static test conditions, OECD 211
	NOEC	Water flea (Daphnia magna)	0.12 mg/l, 21 days
Fish	Growth test LOEC	Fathead minnow (Juvenile Pimephales promelas)	3.09 mg/l, 28 days Flow-through test, OECD 210
	Growth test NOEC	Fathead minnow (Juvenile Pimephales promelas)	1.74 mg/l, 28 days
Other	LOEC	Chironomid (Chironomus riparius)	189.6 mg/l, 28 days Measured, OECD 209
	NOEC	Chironomid (Chironomus riparius)	75.84 mg/l, 28 days
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (Selenastrum capricornutum)	440 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	60 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 24 hours Static test
Fish	EC50	Common carp (Juvenile Cyprinus carpio)	> 10000 mg/l, 72 hours
		Zebra fish (Adult Brachydanio rerio)	5000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	8700 mg/l, 15 minutes
Persistence and degradability			
Photolysis			
Half-life (Photolysis-atmospheric)			
MAGNESIUM STEARATE			17 Hours Estimated
UV/visible spectrum wavelength			
MAGNESIUM STEARATE			210 nm
Biodegradability			
Percent degradation (Aerobic biodegradation-inherent)			
DABRAFENIB MESYLATE			0 %, 28 days OECD 301B, CO2 Evolution, ultimate biodegradation, Activated sludge
			81 %, 28 days OECD 301B, CO2 Evolution, primary degradation, Activated sludge
MAGNESIUM STEARATE			77 %, 28 days BOD

Biodegradability

Percent degradation (Aerobic biodegradation-ready)

MAGNESIUM STEARATE 95 %, 22 days Sturm test

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE 50 %, 13 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

DABRAFENIB MESYLATE 3.38 (measured at pH 7)

Bioconcentration factor (BCF)

DABRAFENIB MESYLATE 3.98 - 4.38 OECD 305, Measured
Species: Rainbow trout (Adult Oncorhynchus mykiss)
MAGNESIUM STEARATE > 9999 Estimated

Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

DABRAFENIB MESYLATE 2.93, pH 7

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE 5.86 Estimated

Mobility in general

Distribution

Octanol/water distribution coefficient log DOW

DABRAFENIB MESYLATE -0.17, pH 9
3.23 Measured., pH 5
3.38, pH 7

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. 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). Avoid discharge into water courses or onto the ground.

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. (DABRAFENIB CAPSULES)
Transport hazard class(es)
Class 9
Subsidiary risk -
Label(s) 9
Packing group III
Environmental hazards
Marine pollutant Yes
Special precautions for user Not available.
Special provisions 8, 146, 335, A112, B54, IB8, IP3, N20, T1, TP33
Packaging exceptions 155
Packaging non bulk 213
Packaging bulk 240

IATA

UN number UN3077
UN proper shipping name Environmentally hazardous substance, solid, n.o.s. (DABRAFENIB CAPSULES)
Transport hazard class(es) 9
Subsidiary class(es) -
Packaging group III

Environmental hazards No.
Labels required 9
ERG Code 9L
Special precautions for user Not available.

Other information

Cargo aircraft only Allowed.
Passenger & cargo Allowed.

IMDG

UN number UN3077
UN proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (DABRAFENIB CAPSULES)

Transport hazard class(es)

Class 9

Subsidiary risk -

Label(s) 9

Packing group III

Environmental hazards

Marine pollutant Yes

EmS F-A, S-F

Special precautions for user Not available.

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



Marine pollutant



General information

Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

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.

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 - Yes
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

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
PREGELATINIZED STARCH (CAS 9005-25-8)
SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)

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

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)

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

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
PREGELATINIZED STARCH (CAS 9005-25-8)
SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)

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.

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

Country(s) or region	Inventory name	On inventory (yes/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	01-20-2014
Revision date	06-03-2015
Version #	14
Further information	HMIS® is a registered trade and service mark of the NPCA. Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.
HMIS® ratings	Health: 3* Flammability: 1 Physical hazard: 0
NFPA ratings	Health: 3 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 Hazard(s) identification: Hazard(s) not otherwise classified (HNOC) Composition / Information on Ingredients: Undisclosed Ingredient Statement Handling and storage: Precautions for safe handling Toxicological information: Carcinogenicity Toxicological information: Further information Toxicological information: Reproductive toxicity Regulatory Information: United States