

1. Identification

Product identifier **MOMELOTINIB TABLETS 100, 150 and 200 MG**

Other means of identification

Synonyms OJJAARA FILM-COATED TABLETS * OMJJARA FILM-COATED TABLETS * MOMELOTINIB FILM-COATED TABLETS * MOMELOTINIB TABLETS, 100mg, 150mg and 200mg * MOMELOTINIB FORMULATED PRODUCT

Recommended use Bulk Formulated Product
Medicinal Product.

This safety data sheet (SDS) has been prepared in accordance with workplace safety standards which require identification of all known hazards of the material regardless of potential risk. The information is intended for people handling the material in the workplace. Warnings included may not apply in all cases. Needs may vary depending upon the potential for exposure in the workplace. The SDS is not intended to provide information relevant to final use of the material for the purpose intended. Consumers/Patients should consult prescribing information/package insert/product label or consult their chemist or physician.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

COMPANY NAME GSK

Address: 410 Blackwell Street
Durham, NC, 27701

Telephone: +1-888-825-5249 (GSK General Inquiries)
+1-877-844-8872 (ViiV General Inquiries)

Email: msds@gsk.com

Website: www.gsk.com

EMERGENCY CONTACTS

Telephone: 3E GLOBAL INCIDENT RESPONSE
+(1) 760 476 3971 (In country)
+(1) 760 476 3962 or +(1) 866 519 4752 (International)
24/7; multi-language response

Contract Number: 334878

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Serious eye damage/eye irritation	Category 1
	Reproductive toxicity	Category 2
	Specific target organ toxicity, repeated exposure	Category 2 (blood, kidneys, lymphatic system, reproductive system)
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	

Label elements



Signal word Danger

Hazard statement	Causes serious eye damage. Suspected of damaging fertility or the unborn child. May cause damage to organs (blood, kidneys, lymphatic system, reproductive system) through prolonged or repeated exposure.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If on skin: Wash with plenty of water/soap. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor/physician. Specific treatment (see instructions on this label). Wash contaminated clothing before reuse.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	Assume that this material is capable of sustaining combustion. Caution - Pharmaceutical agent. See section 11 of the SDS for additional information on health hazards.
Supplemental information	52.75% of the mixture consists of component(s) of unknown acute oral toxicity. 100% of the mixture consists of component(s) of unknown acute dermal toxicity. 100% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 100% of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
MOMELOTINIB DIHYDROCHLORIDE MONOHYDRATE	MOMELOTINIB DIHYDROCHLORIDE HYDRATE GSK3070785B	1380317-28-1	40.65
MICROCRYSTALLINE CELLULOSE	AVICEL PH MICROCRYSTALLINE CELLULOSE ALPHA-CELLULOSE AVICEL PH101 AVICEL PH102 AVICEL PH103 AVICEL PH105 AVICEL PH112 AVICEL PH200 AVICEL 1030W CELLULOSE (8CI9CI) CELLULOSE CRYSTALLINE CELLULOSE, FOOD GRADE CELPHERE CP203 CEOLUS KG-802 CRYSTALLINE CELLULOSE VIVAPUR VIVAPUR 101 VIVAPUR 102 VIVAPUR 112 VIVAPUR 200	9004-34-6	34.23
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE	557-04-0	1.5
POLYETHYLENE GLYCOL (SOLID)	Carbowax PEG 8000 ETHYLENE GLYCOL HOMOPOLYMER ETHYLENE GLYCOL POLYMER PEG 3350 PEG 3400 PEG 8000 POLYETHYLENE GLYCOL 3350 POLYETHYLENE GLYCOL 3400 POLYETHYLENE GLYCOL 8000 POLYGLYCOL E-8000 POLYOXYETHYLENE 8000	25322-68-3	0.808

Chemical name	Common name and synonyms	CAS number	%
TITANIUM DIOXIDE	TITANIUM OXIDE TITANIUM(IV) OXIDE TITANIUM PEROXIDE (TiO2) PIGMENT WHITE 6	13463-67-7	0.6108
TALC, NON-ASBESTOS FORM	AGALITE CIRCRO MP CRYSTALITE CRS 6002 CROWN TALC W 83 CROWN TALC Z CUBIC MASTER DESERTALC 57 EMTAL 500 EMTAL 549 EMTAL 596 EMTAL 599 FIBRENE C 400 FINNTALC PF IT EXTRA MICRO ACE K1 MICRO ACE L1 MICRON WHITE 5000A MICRON WHITE 5000P MICRON WHITE 5000S MICROTALCO IT EXTRA MISTRON FROST P MISTRON STAR MISTRON SUPER FROST MUSSOLINITE NYTAL 200 NYTAL 400 POLYTAL 4641 POLYTAL 4725 SILICATE: TALC, CONTAINING NO ASBESTOS (OSHA) STEAWHITE SUPREME TALC (ACGIH) TALCAN PK-P TALCRO CP 44-31 TALCUM TALC - NON-ASBESTOS FORM	14807-96-6	0.592
PROPYL GALLATE	BENZOIC ACID, 3,4,5-TRIHIDROXY-, PROPYL ESTER NIPA 49 NIPAGALLIN P PROGALLIN P PROPYLESTER KYSELINY GALLOVE (CZECH) N-PROPYL ESTER OF 3,4,5-TRIHIDROXYBENZOIC ACID PROPYL GALLATE N-PROPYL GALLATE PROPYL 3,4,5-TRIHIDROXYBENZOAT E N-PROPYL 3,4,5- TRIHIDROXYBENZOATE TENOX PG 3,4,5-TRIHIDROXYBENZENE-1- PROPYLCARBOXYLATE 3,4,5-TRIHIDROXYBENZOIC ACID N-PROPYL ESTER	121-79-9	0.2

Chemical name	Common name and synonyms	CAS number	%
FERRIC OXIDE RED	IRON OXIDE (Fe ₂ O ₃) C.I. 77491 C.I. PIGMENT RED 101 SICOVET RED 30 DIIRON TRIOXIDE IRON(III) OXIDE IRON OXIDE IRON(3+) OXIDE IRON OXIDE RED IRON SESQUIOXIDE IRON TRIOXIDE RED IRON OXIDE HEMATITE GAMMA-IRON OXIDE (Fe ₂ O ₃)	1309-37-1	0.0728
Other components below reportable levels			21.3364

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately.
Ingestion	Rinse mouth. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	The following adverse effects have been noted with therapeutic use of this material: Dizziness. Fatigue. Nausea. Diarrhea. Causes serious eye damage. Prolonged exposure may cause chronic effects. Product dust may be irritating to eyes, skin and respiratory system.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
General information	IF exposed or concerned: Get medical advice/attention. If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before reuse. 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.

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. Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	Assume that this material is capable of sustaining combustion. 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. 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.
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Methods and materials for containment and cleaning up

Large Spills: Stop the flow of material, if this is without risk. Following product recovery, flush area with water.

Small Spills: Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. Put material in suitable, covered, labeled containers. For waste disposal, see section 13 of the SDS.

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 get this material in contact with eyes. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Should be handled in closed systems, if possible. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

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

8. Exposure controls/personal protection**Occupational exposure limits**

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

GSK

Components	Type	Value	Form
FERRIC OXIDE RED (CAS 1309-37-1)	OHC	1	
MOMELOTINIB DIHYDROCHLORIDE MONOHYDRATE (CAS 1380317-28-1)	8 HR TWA	50 mcg/m3	
	OHC	3	REPRODUCTIVE HAZARD
	PDE	500 mcg/day	Oral
		250 mcg/day	Parenteral, Inhalation
POLYETHYLENE GLYCOL (SOLID) (CAS 25322-68-3)	OHC	1	

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

Components	Type	Value	Form
FERRIC OXIDE RED (CAS 1309-37-1)	PEL	10 mg/m3	Fume.
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
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
FERRIC OXIDE RED (CAS 1309-37-1)	TWA	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.
TALC, NON-ASBESTOS FORM (CAS 14807-96-6)	TWA	0.1 mg/m3	Respirable.
		20 mppcf	
		2.4 mppcf	Respirable.
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	5 mg/m3	Respirable fraction.

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

Components	Type	Value	Form
		15 mg/m3	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
FERRIC OXIDE RED (CAS 1309-37-1)	TWA	5 mg/m3	Respirable fraction.
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	3 mg/m3	Respirable fraction.
		10 mg/m3	Inhalable fraction.
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3	
TALC, NON-ASBESTOS FORM (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
FERRIC OXIDE RED (CAS 1309-37-1)	TWA	5 mg/m3	Dust and fume.
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total
TALC, NON-ASBESTOS FORM (CAS 14807-96-6)	TWA	2 mg/m3	Respirable.

US. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
POLYETHYLENE GLYCOL (SOLID) (CAS 25322-68-3)	TWA	10 mg/m3	Aerosol.

Biological limit values

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

Appropriate engineering controls

Good general ventilation 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. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection

Not normally needed. Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection

Not normally needed. Wear appropriate chemical resistant gloves.

Other

Not normally needed. Wear suitable protective clothing.

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

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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

Health surveillance should be determined by risk assessment in consultation with Occupational Health. Local regulatory requirements must be adhered to.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Coated tablet
Color	Brown
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	
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.
Other information	
Explosive properties	Not established.
Oxidizing properties	Not established.

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 product's decomposition. No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Dust may irritate respiratory system. Prolonged inhalation may be harmful.
Skin contact	Dust or powder may irritate the skin. May cause an allergic skin reaction. Prolonged skin contact may cause temporary irritation.
Eye contact	Dust in the eyes will cause irritation. Causes serious eye damage.
Ingestion	May cause discomfort if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics	The following adverse effects have been noted with therapeutic use of this material: Dizziness. Fatigue. Nausea. Diarrhea. Causes serious eye damage. Prolonged exposure may cause chronic effects. May cause an allergic skin reaction. Product dust may be irritating to eyes, skin and respiratory system.
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Information on toxicological effects

Acute toxicity	Expected to be a low hazard for usual industrial or commercial handling by trained personnel.
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Components	Species	Test Results
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
POLYETHYLENE GLYCOL (SOLID) (CAS 25322-68-3)		
Acute		
Oral		
LD50	Rat	10000 mg/kg
PROPYL GALLATE (CAS 121-79-9)		
Acute		
Oral		
LD50	Rat	2100 mg/kg
TALC, NON-ASBESTOS FORM (CAS 14807-96-6)		
Acute		
Inhalation		
NOAEL	Rat	10.8000000000000007 mg/m3
TITANIUM DIOXIDE (CAS 13463-67-7)		
Acute		
Inhalation		
LC50	Rat	6820 mcg/m3
Oral		
LD50	Rat	> 24 g/kg
Chronic		
Inhalation		
LOEC	Rat	8.5999999999999996 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		
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	3.2000000000000002 - 20 mg/m3, 8 min Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation. Dust or powder may irritate the skin.

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

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

0

Serious eye damage/eye irritation Dust in the eyes will cause irritation. Causes serious eye damage.

Eye

TITANIUM DIOXIDE

OECD 405, Literature data
Result: Mild irritant
Species: Rabbit

Eye / Kay and Calandra class - Intact
MAGNESIUM STEARATE

4

Recovery Period: 2 days

Respiratory or skin sensitization

Not likely, due to the form of the product. The product contains a small amount of sensitizing substance which may provoke an allergic reaction among sensitive individuals in contact with skin.

Respiratory sensitization

Due to partial or complete lack of data the classification is not possible. Dust may irritate respiratory system.

Skin sensitization

Prolonged skin contact may cause temporary irritation. 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

Health injuries are not expected as a result of occupational exposure or intended use.

Mutagenicity

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
Syrian Hamster Embryo (SHE) cell transformation assay
Result: Negative
WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data
Result: Positive

Carcinogenicity

Carcinogenic effects are not expected as a result of occupational exposure. Contains a material (titanium dioxide and talc) classified 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 - Literature data.
Result: Negative
Species: Rat

Carcinogenicity

TITANIUM DIOXIDE

25000 - 50000 ppm, Dietary study

Result: Negative

Species: Mouse

7.2 - 14.8 mg/m³, Literature data

Result: Lung tumour

Species: Rat

Test Duration: 24 months

IARC Monographs. Overall Evaluation of Carcinogenicity

FERRIC OXIDE RED (CAS 1309-37-1)

3 Not classifiable as to carcinogenicity to humans.

TALC, NON-ASBESTOS FORM (CAS 14807-96-6)

2B Possibly carcinogenic to humans.

TITANIUM DIOXIDE (CAS 13463-67-7)

3 Not classifiable as to carcinogenicity to humans.

2B Possibly carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Specific target organ toxicity - single exposure

Not classified. Due to partial or complete lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure

May cause damage to organs (blood, kidneys, lymphatic system, reproductive system) through prolonged or repeated exposure.

Aspiration hazard

Not likely, due to the form of the product. Due to partial or complete lack of data the classification is not possible.

Chronic effects

Causes damage to organs through prolonged or repeated exposure. Prolonged exposure may cause chronic effects.

Further information

Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

Health surveillance should be determined by risk assessment in consultation with Occupational Health. Local regulatory requirements must be adhered to.

12. Ecological information**Ecotoxicity**

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components	Species	Test Results
FERRIC OXIDE RED (CAS 1309-37-1)		
Aquatic		
<i>Acute</i>		
Fish	EC50	Golden ide/orfe (Adult Leuciscus idus)
		> 1000 mg/l, 48 hours Static test
<i>Chronic</i>		
Other	EC50	Bacteria
		> 5000 mg/l, 24 hours
MAGNESIUM STEARATE (CAS 557-04-0)		
Aquatic		
<i>Acute</i>		
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)
		130 mg/l, 96 hours
POLYETHYLENE GLYCOL (SOLID) (CAS 25322-68-3)		
Aquatic		
<i>Acute</i>		
Fish	EC50	Goldfish (Adult Carassius auratus)
		> 50000 mg/L, 24 hours
Microtox	EC50	Microtox
		> 100000 mg/L, 15 minutes
TALC, NON-ASBESTOS FORM (CAS 14807-96-6)		
Aquatic		
<i>Acute</i>		
Fish	EC50	Zebra fish (Adult Brachydanio rerio)
		> 100 g/l, 24 hours Static renewal test

Components	Species	Test Results
TITANIUM DIOXIDE (CAS 13463-67-7)		
Aquatic		
Fish	LC50	Mummichog (<i>Fundulus heteroclitus</i>) > 1000 mg/l, 96 hours
<i>Acute</i>		
Crustacea	EC50	Water flea (<i>Daphnia magna</i>) > 1000 mg/l, 48 hours Static test
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-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)		
PROPYL GALLATE		1.8
Bioconcentration factor (BCF)		
MAGNESIUM STEARATE		> 9999 Estimated
Mobility in soil	No data available.	
Adsorption		
Soil/sediment sorption - log Koc		
MAGNESIUM STEARATE		5.86 Estimated
Mobility in general		
Volatility		
Henry's law		
PROPYL GALLATE		0 atm m ³ /mol, 25 C Estimated
Other adverse effects	Not established.	
13. Disposal considerations		
Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Incinerate the material under controlled conditions in an approved incinerator. 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	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.	
14. Transport information		
DOT		
Not regulated as a dangerous good.		
Read safety instructions, SDS and emergency procedures before handling.		
IATA		
Not regulated as dangerous goods.		
IMDG		
Not regulated as dangerous goods.		
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.	

15. Regulatory information

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

Toxic Substances Control Act (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 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

Yes

Classified hazard categories

Serious eye damage or eye irritation
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

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. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

TALC, NON-ASBESTOS FORM (CAS 14807-96-6)

TITANIUM DIOXIDE (CAS 13463-67-7)

California Proposition 65



WARNING: This product can expose you to TITANIUM DIOXIDE, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California Proposition 65 - CRT: Listed date/Carcinogenic substance

TALC, NON-ASBESTOS FORM (CAS 14807-96-6) Listed: April 1, 1990

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 Industrial Chemicals (AICIS)	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)*
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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	11-02-2022
Revision date	08-25-2023
Version #	04
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 First-aid measures: Most important symptoms/effects, acute and delayed Exposure controls/personal protection: General hygiene considerations Physical and chemical properties: Color Physical and chemical properties: Form Toxicological information: Further information Toxicological information: Symptoms related to the physical, chemical and toxicological characteristics