SAFETY DATA SHEET

1. Identification

Product identifier **IMITREX TABLETS**

Other means of identification

Synonyms IMITREX TABLETS 25 MG * IMITREX TABLETS 50 MG * IMIGRAN TABLETS 50 MG * IMIGRAN CINCUENTA * IMIGRAN TABLETS 100 MG * IMIGRANE TABLETS * IMITREX DF * ROSEMIG * SUMATRIPTAN * SUMATRIPTAN SUCCINATE, 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

COMPANY NAME GlaxoSmithKline US

Address: 5 Moore Drive
Research Triangle Park, NC 27709 USA

Telephone: +1-888-825-5249 (General Inquiries)

Email: msds@gsk.com

Website: www.gsk.com

EMERGENCY CONTACTS

CHEMTREC EMERGENCY NUMBERS

Telephone: +(1) 703 527 3887 (International)
24/7; multi-language response

Contract Number: CCN9484

VERISK 3E GLOBAL INCIDENT RESPONSE

Telephone: +(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

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	%
LACTOSE, MONOHYDRATE	D-LACTOSE LACTOSE MONOHYDRATE NF ALPHA-LACTOSE A-LACTOSE MILK SUGAR LACTOHALE 200 ALPHA-LACTOSE MONOHYDRATE	64044-51-5	40 - < 65

Chemical name	Common name and synonyms	CAS number	%
SUMATRIPTAN SUCCINATE	GR 43175C 3-(2-(DIMETHYLAMINO)ETHYL)-N-MET HYL-1H-INDOLE-5-METHANESULPHON AMIDE SUCCINATE 357 (GW ACN) 455 SUMATRIPTAN STANDARD REFERENCE TEST MIX 1 (ANZ) 6666 SUMATRIPTAN STANDARD REFERENCE TEST MIX 12 (ANZ) 466 SUMATRIPTAN STANDARD REFERENCE TEST MIX 13 (ANZ) 599 SUMATRIPTAN STANDARD REFERENCE TEST MIX 18 (ANZ)	103628-48-4	21.0 - 41.0
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	4.55
POLYETHYLENE GLYCOL	AZIRIDINE, HOMOPOLYMER, ETHOXYLATED OHS19172 POLYETHYLENEIMINE ETHOXYLATE	68130-99-4	3 - < 5
TITANIUM DIOXIDE	TITANIUM OXIDE TITANIUM(IV) OXIDE TITANIUM PEROXIDE (TiO2) PIGMENT WHITE 6	13463-67-7	3 - < 5
CROSCARMELLOSE SODIUM	AC-DI-SOL (R) SODIUM CROSCARMELLOSE AC-DI-SOL (R) CROSCARMELLOSE SODIUM AC-DI-SOL (R) SD-711	74811-65-7	0.9
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE	557-04-0	0.5
POLYETHYLENE GLYCOLS	GLYCOLS, POLYETHYLENE ETHYLENE GLYCOL HOMOPOLYMER ETHYLENE GLYCOL POLYMER ETHYLENE OXIDE POLYMER ETHYLENE POLYOXIDE ALPHA, OMEGA-HYDROXYPOLY(ETHYLENE OXIDE) POLY(ETHYLENE OXIDES) POLY(ETHYLENE ETHER) GLYCOL ALPH-HYDRO-OMEGA-HYDROXY POLY(OXY-1,2-ETHANEDIYL) POLYETHYLENE GLYCOL POLY(VINYL OXIDE) 1,2-ETHANEDIOL, MONOPOLYMER POLYETHYLENE OXIDE OXIRANE POLYMER CARBOWAX PEG PEG-100 PEG-4 PEG-40 MACROGOL	25322-68-3	< 1

*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	The following adverse effects have been noted with therapeutic use of this material: abnormal nervous system sensations; feelings of heaviness or pressure; weakness. Difficulty in breathing. Drowsiness and dizziness. Fatigue. Nausea, vomiting.
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 center.
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 (CO2).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
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. Wear appropriate protective equipment and clothing during clean-up. 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	Prevent product from entering drains. Stop the flow of material, if this is without risk. Following product recovery, flush area with water. Put material in suitable, covered, labeled containers. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in a well-ventilated place. 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

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	Note
CROSCARMELLOSE SODIUM (CAS 74811-65-7)	OHC	1	>1000 - </=5000 mcg/m3 PROVISIONAL
LACTOSE, MONOHYDRATE (CAS 64044-51-5)	OHC	1	>1000 - </=5000 mcg/m3 PROVISIONAL
POLYETHYLENE GLYCOL (CAS 68130-99-4)	OHC	1	>1000 - </=5000 mcg/m3 PROVISIONAL
SUMATRIPTAN SUCCINATE (CAS 103628-48-4)	15 MIN STEL	100 mcg/m3	
	8 HR TWA	50 mcg/m3	
	OHC	3	REPRODUCTIVE HAZARD

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.
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
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

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
TITANIUM DIOXIDE (CAS 13463-67-7)	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

US. AIHA Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
POLYETHYLENE GLYCOLS (CAS 25322-68-3)	TWA	10 mg/m3	Particulate.

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

Exposure guidelines

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	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.

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.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's 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.
Skin contact	Health injuries are not known or expected under normal use.
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. 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:; abnormal nervous system sensations;; feelings of heaviness or pressure; weakness. Difficulty in breathing. Drowsiness and dizziness. Fatigue. Nausea, vomiting.

Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
CROSCARMELLOSE SODIUM (CAS 74811-65-7)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Inhalation		
LCLo	Rat	> 0.1 mg/l
Oral		
LD50	Rat	5050 mg/kg
LACTOSE, MONOHYDRATE (CAS 64044-51-5)		
Acute		
Oral		
LD50	Rat	> 10 g/kg
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 GLYCOLS (CAS 25322-68-3)		
Acute		
Oral		
LD50	Rat	10000 mg/kg
SUMATRIPTAN SUCCINATE (CAS 103628-48-4)		
Acute		
Oral		
LD50	Mouse	> 1500 mg/kg
	Rat	> 2000 mg/kg
Chronic		
Oral		
NOAEL	Rat	5 mg/kg/day, 18 months
TD	Rat	>= 50 mg/kg/day

Components	Species	Test Results
Subchronic		
Oral		
TD	Dog	<= 50 mg/kg/day, 60 weeks
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.

* 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

SUMATRIPTAN SUCCINATE	Acute dermal irritation Result: Negative

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 Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

Eye

SUMATRIPTAN SUCCINATE	OECD 405 Result: Mild irritant Species: Rabbit

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

Respiratory sensitization No studies have been conducted.

Skin sensitization None known. This product is not expected to cause skin sensitization.

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
SUMATRIPTAN SUCCINATE	Topical Result: Negative Species: Guinea pig

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

SUMATRIPTAN SUCCINATE	<= 1000 mg/kg Micronucleus Test Result: Negative Species: Rat Ames, GLP Result: Negative
TITANIUM DIOXIDE	Ames, Literature data Result: Negative
SUMATRIPTAN SUCCINATE	Bacterial Fluctuation Test Result: Negative Chromosomal Aberration Assay In Vitro, GLP Result: Negative HPRT gene mutation in human lymphocytes Result: Negative
TITANIUM DIOXIDE	Micronucleus Assay in vitro, CHO cells, Literature data Result: Negative Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data Result: Positive Syrian Hamster Embryo (SHE) cell transformation assay Result: Negative
SUMATRIPTAN SUCCINATE	WHO Nitrosation Assay Result: Negative
TITANIUM DIOXIDE	WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data Result: Positive
SUMATRIPTAN SUCCINATE	Yeast Mutation Assay Result: Negative

Carcinogenicity Carcinogenic effects are not expected as a result of occupational exposure. Contains a material (titanium dioxide) classified as a carcinogen by external agencies. These effects are linked only to high doses of this substance; lower doses did not cause this adverse effect.

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
SUMATRIPTAN SUCCINATE	10 - 160 mg/kg/day Result: Negative Species: Mouse

Carcinogenicity

SUMATRIPTAN SUCCINATE	10 - 160 mg/kg/day Result: Negative Species: Rat
TITANIUM DIOXIDE	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 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

TITANIUM DIOXIDE (CAS 13463-67-7)	2B Possibly carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.

Reproductivity

SUMATRIPTAN SUCCINATE	>= 100 mg/kg/day Embryo-foetal development - Oral Result: Maternal toxicity; adverse foetal effects Species: Rat >= 100 mg/kg/day Embryo-foetal development- Oral Result: Maternal toxicity; adverse foetal effects Species: Rabbit 100 mg/kg/day Fertility Result: Reduced success of insemination. Species: Rat 1000 mg/kg/day Pre- and Post-natal development Result: Maternal toxicity; adverse foetal effects 50 mg/kg/day Embryo-foetal development- Oral Result: NOAEL Species: Rabbit 60 mg/kg/day Embryo-foetal development - Oral Result: NOAEL Species: Rabbit

Specific target organ toxicity - single exposure Circulatory system.

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

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

Chronic effects 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.

12. Ecological information

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

Components		Species	Test Results
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
SUMATRIPTAN SUCCINATE (CAS 103628-48-4)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 750 mg/l, 3 hours OECD 209
Algae	EC50	Green algae (Scenedesmus subspicatus)	36 mg/l, 72 hours OECD 201
	NOEC	Green algae (Scenedesmus subspicatus)	12.5 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia pulex)	290 mg/l, 48 hours Static test, OECD 202
	NOEC	Water flea (Daphnia pulex)	200 mg/l, 48 hours
Fish	EC50	Rainbow trout (Juvenile Oncorhyncus mykiss)	> 100 mg/l, 96 hours OECD 203
	NOEC	Rainbow trout (Juvenile Oncorhyncus mykiss)	100 mg/l, 96 hours
Chronic			
Crustacea	LOEC	Water flea (Ceriodaphnia dubia)	100 mg/l, 8 days Static renewal test, EPA Method 1002
	NOEC	Daphnia	32 mg/l, 8 days
TITANIUM DIOXIDE (CAS 13463-67-7)			
Aquatic			
Fish	LC50	Mummichog (Fundulus heteroclitus)	> 1000 mg/l, 96 hours
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours Static test

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

Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE	17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE	210 nm
SUMATRIPTAN SUCCINATE	290 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

SUMATRIPTAN SUCCINATE	> 1 Years Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

MAGNESIUM STEARATE	77 %, 28 days BOD
SUMATRIPTAN SUCCINATE	100 %, 16 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge 17 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge

Percent degradation (Aerobic biodegradation-ready)

MAGNESIUM STEARATE	95 %, 22 days Sturm test
SUMATRIPTAN SUCCINATE	1 %, 28 days

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE	50 %, 13 days
SUMATRIPTAN SUCCINATE	32 - 40 %, 64 days, Soil

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

SUMATRIPTAN SUCCINATE	0.93 (Measured).

Bioconcentration factor (BCF)

MAGNESIUM STEARATE	> 9999 Estimated

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

LACTOSE, MONOHYDRATE	1 Calculated
MAGNESIUM STEARATE	5.86 Estimated
SUMATRIPTAN SUCCINATE	3.52 - 3.57 Measured

Mobility in general

Volatility

Henry's law

LACTOSE, MONOHYDRATE	< 0 atm m3/mol Calculated

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable 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). Avoid discharge into water courses or onto the ground.

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.

Not available.

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

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 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

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 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

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

TITANIUM DIOXIDE (CAS 13463-67-7)

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
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 05-24-2018

Revision date 05-24-2018

Version # 13

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.