



# SAFETY DATA SHEET

## 1. Identification

**Product identifier**

**IMITREX FDT TABLETS**

**Other means of identification**

**Synonyms**

IMITREX INSTANT \* IMITREX DF \* IMIGRAN RADIS \* IMIGRAN FDT \* IMIGRAN DR \* IMIGRAN SPRINT \* IMIGRAN T \* IMIGRAN NEO \* IMIGRAN NOVUM \* IMIGRAN T 50 MG FILMTABLETTEN \* IMIGRAN T 100 MG FILMTABLETTEN \* ROSEMIG \* SUMATRIPTAN FAST DISINTEGRATING TABLETS (FDT) \* SUMATRIPTAN SUCCINATE FAST DISINTERGRATING DISPERSIBLE TABLET \* SUMATRIPTAN FDT 25 MG TABLETS \* SUMATRIPTAN FDT 50 MG TABLETS \* SUMATRIPTAN FDT 100 MG TABLETS \* SUMATRIPTAN SPIRIG HC \* 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**

**Telephone:**

CHEMTREC EMERGENCY NUMBERS

+(1) 703 527 3887 (International)

24/7; multi-language response

**Contract Number:**

CCN9484

**Telephone:**

VERISK 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

**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	14 - < 45
CALCIUM PHOSPHATE, DIBASIC	CALCIUM ACID PHOSPHATE CALCIUM HYDROGEN ORTHOPHOSPHATE CALCIUM HYDROGEN PHOSPHATE CALCIUM MONOHYDROGEN PHOSPHATE CALCIUM ORTHOPHOSPHATE (CAHPO4) DIBASIC CALCIUM PHOSPHATE DICALCIUM ORTHOPHOSPHATE DICALCIUM PHOSPHATE MONOCALCIUM ACID PHOSPHATE CALCIUM PHOSPHATE	7757-93-9	19.6 - 34.3
SUMATRIPTAN SUCCINATE	GR 43175C 3-(2-(DIMETHYLAMINO)ETHYL)-N-METHYL-1H-INDOLE-5-METHANESULPHONAMIDE 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	19.6 - 34.3
SODIUM BICARBONATE	BAKING SODA BICARBONATE OF SODA CARBONIC ACID MONOSODIUM SALT CARBONIC ACID SODIUM SALT (1:1) MONOSODIUM CARBONATE MONOSODIUM HYDROGEN CARBONATE RTECS VZ0950000 SODIUM ACID CARBONATE SODIUM HYDROGEN CARBONATE	144-55-8	9 - < 15
CROSCARMELLOSE SODIUM	AC-DI-SOL (R) SODIUM CROSCARMELLOSE AC-DI-SOL (R) CROSCARMELLOSE SODIUM AC-DI-SOL (R) SD-711	74811-65-7	4.9
POLYETHYLENE GLYCOL	AZIRIDINE, HOMOPOLYMER, ETHOXYLATED OHS19172 POLYETHYLENEIMINE ETHOXYLATE	68130-99-4	1 - < 3
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE	557-04-0	0.5
TITANIUM DIOXIDE	TITANIUM OXIDE TITANIUM(IV) OXIDE TITANIUM PEROXIDE (TiO2) PIGMENT WHITE 6	13463-67-7	< 1

Chemical name	Common name and synonyms	CAS number	%
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	< 0.2
FERRIC OXIDE RED	IRON OXIDE (Fe <sub>2</sub> O <sub>3</sub> ) C.I. 77491 C.I. PIGMENT RED 101 CROCUS(IRON OXIDE) DIIRON TRIOXIDE FERRIC OXIDE IRON(III) OXIDE IRON OXIDE IRON(3+) OXIDE IRON OXIDE RED IRON SESQUIOXIDE IRON TRIOXIDE JEWELER'S ROUGE RED IRON OXIDE HEMATITE TURKEY RED ALPHA-FERRIC OXIDE ALPHA-IRON OXIDE GAMMA-FERRIC OXIDE GAMMA-IRON OXIDE (Fe <sub>2</sub> O <sub>3</sub> ) Fe <sub>2</sub> O <sub>3</sub> RTECS NO7400000	1309-37-1	< 0.1

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

#### 4. First-aid measures

<b>Inhalation</b>	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.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	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.
<b>Most important symptoms/effects, acute and delayed</b>	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.
<b>Indication of immediate medical attention and special treatment needed</b>	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** Observe good industrial hygiene practices. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid release to the environment.

**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.

<b>GSK Components</b>	<b>Type</b>	<b>Value</b>	<b>Note</b>
CALCIUM PHOSPHATE, DIBASIC (CAS 7757-93-9)	OHC	1	
CROSCARMELLOSE SODIUM (CAS 74811-65-7)	OHC	1	>1000 - </=5000 mcg/m3 PROVISIONAL
FERRIC OXIDE RED (CAS 1309-37-1)	OHC	1	
POLYETHYLENE GLYCOL (CAS 68130-99-4)	OHC	1	>1000 - </=5000 mcg/m3 PROVISIONAL
SODIUM BICARBONATE (CAS 144-55-8)	8 HR TWA	5000 mcg/m3	
	OHC	1	
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
FERRIC OXIDE RED (CAS 1309-37-1)	PEL	10 mg/m3	Fume.
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	PEL	5 mg/m3	Respirable fraction.
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	15 mg/m3	Total dust.
		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.
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	Form
FERRIC OXIDE RED (CAS 1309-37-1)	TWA	5 mg/m3	Respirable fraction.
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
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

**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** 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. 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.

<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	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

<b>Physical state</b>	Solid.
<b>Form</b>	Tablet.
<b>Color</b>	Not available.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidizing properties</b>	Not oxidizing.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents. Fluorine.
<b>Hazardous decomposition products</b>	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

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
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**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
CALCIUM PHOSPHATE, DIBASIC (CAS 7757-93-9)		
<b>Acute</b>		
<b>Dermal</b>		
LD50	Rabbit	> 7940 mg/kg
<b>Oral</b>		
LD50	Rat	> 10 g/kg
CROSCARMELLOSE SODIUM (CAS 74811-65-7)		
<b>Acute</b>		
<b>Dermal</b>		
LD50	Rabbit	> 2000 mg/kg
<b>Inhalation</b>		
LCLo	Rat	> 0.1 mg/l
<b>Oral</b>		
LD50	Rat	5050 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	> 2000 mg/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
<b>Acute</b>		
<b>Dermal</b>		
LD50	Rabbit	> 2000 mg/kg
<b>Oral</b>		
LD50	Rat	> 2000 mg/kg
POLYETHYLENE GLYCOLS (CAS 25322-68-3)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	10000 mg/kg
SODIUM BICARBONATE (CAS 144-55-8)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	>= 7300 mg/kg
SUMATRIPTAN SUCCINATE (CAS 103628-48-4)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Mouse	> 1500 mg/kg
	Rat	> 2000 mg/kg
<b>Chronic</b>		
<b>Oral</b>		
NOAEL	Rat	5 mg/kg/day, 18 months

Components	Species	Test Results
TD	Rat	>= 50 mg/kg/day
<b><u>Subchronic</u></b>		
<b>Oral</b>		
TD	Dog	<= 50 mg/kg/day, 60 weeks
TITANIUM DIOXIDE (CAS 13463-67-7)		
<b><u>Acute</u></b>		
<b>Inhalation</b>		
LC50	Rat	6820 mcg/m3
<b>Oral</b>		
LD50	Rat	> 24 g/kg
<b><u>Chronic</u></b>		
<b>Inhalation</b>		
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
<b><u>Subacute</u></b>		
<b>Inhalation</b>		
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.
<b>Oral</b>		
NOAEL	Rat	100000 ppm, 14 Day Dietary study, highest dose tested.
<b><u>Subchronic</u></b>		
<b>Inhalation</b>		
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

TITANIUM DIOXIDE

Ames, GLP  
Result: Negative  
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/m<sup>3</sup>, 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/m<sup>3</sup>, 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.

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

Prolonged inhalation may be harmful. Prolonged exposure may cause chronic effects.

## 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
<b>FERRIC OXIDE RED (CAS 1309-37-1)</b>		
<b>Aquatic</b>		
<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
<b>MAGNESIUM STEARATE (CAS 557-04-0)</b>		
<b>Aquatic</b>		
<i>Acute</i>		
Fish	EC50	Orange-red killfish (Adult Oryzias latipes) 130 mg/l, 96 hours
<b>SODIUM BICARBONATE (CAS 144-55-8)</b>		
<b>Aquatic</b>		
<i>Acute</i>		
Algae	EC50	Algae (Nitscheria linearis) 650 mg/l, 5 days
Crustacea	EC50	Water flea (Daphnia magna) 2350 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus) 8250 - 9000 mg/l, 96 hours Static test
		Mosquito fish (Adult Gambusia affinis) 7550 mg/l, 96 hours Static test
<b>SUMATRIPTAN SUCCINATE (CAS 103628-48-4)</b>		
<b>Aquatic</b>		
<i>Acute</i>		
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 Oncorhynchus mykiss) > 100 mg/l, 96 hours OECD 203
	NOEC	Rainbow trout (Juvenile Oncorhynchus mykiss) 100 mg/l, 96 hours
<i>Chronic</i>		
Crustacea	LOEC	Water flea (Ceriodaphnia dubia) 100 mg/l, 8 days Static renewal test, EPA Method 1002
	NOEC	Daphnia 32 mg/l, 8 days
<b>TITANIUM DIOXIDE (CAS 13463-67-7)</b>		
<b>Aquatic</b>		
Fish	LC50	Mummichog (Fundulus heteroclitus) > 1000 mg/l, 96 hours
<i>Acute</i>		
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

MAGNESIUM STEARATE 5.86 Estimated  
SUMATRIPTAN SUCCINATE 3.52 - 3.57 Measured

**Mobility in general** Not applicable.

**Other adverse effects** Not available.

## 13. Disposal considerations

<b>Disposal instructions</b>	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.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	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.
<b>Contaminated packaging</b>	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** 05-17-2018  
**Revision date** 05-17-2018  
**Version #** 10  
**Further information** HMIS® is a registered trade and service mark of the NPCA.

**HMIS® ratings**

Health: 2\*  
Flammability: 0  
Physical hazard: 0

**NFPA ratings**

Health: 2  
Flammability: 0  
Instability: 0

**References**

GSK Hazard Determination

**Disclaimer**

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

**Revision information**

This document has undergone significant changes and should be reviewed in its entirety.