

Section 1: Identification		
Common Name/Trade Name	Sumatriptan Succinate USP	
Supplier Information	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	IN CASE OF EMERGENCY: Chemtrec 1 (800) 424-9300 (24 hours)
Product Synonym(s)	Sumatriptan Succinate, 1H-Indole-5-methanesulfonamio	de, 3-[2-(dimethylamino)ethyl]-N-methyl-, butanedioate (1:1)
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification		
Classification of Substance or Mixture	Serious eye damage/eye irritation, Category 2B, Sensitization, respiratory, Category 1, Sensitiztion, skin, Category 1	
Signal Word	Danger	
Hazard Statement(s)	H317 H320 H334	May cause an allergic skin reaction Causes eye irritation May cause allergy or asthma symptoms or breathing difficulties if inhaled
Pictogram(s)		
Precautionary Statement(s)	P261 P264 P272 P280 P285 P302+P352 P304+P341 P305+P351+P338 P333+P313 P337+P313 P342+P311 P363 P501	Avoid breathing dust/fume/gas/mist/vapours/spray. Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. IF ON SKIN Wash with soap and water. IF INHALED If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. IF IN EYES Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. continue rinsing. If skin irritation or a rash occurs Get medical advice/attention. If eye irritation persists Get medical advice/attention. If experiencing respiratory symptoms Call a POISON CENTER or doctor/physician. Wash contaminated clothing before reuse. Dispose of contents/container to an approved waste disposal plant.
Hazards Not Otherwise Classified	The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.	
Ingredient(s) with Unknown Toxicity	No data available	

Section 3: Composition/Information on Ingredients	
Chemical Name	1H-Indole-5-methanesulfonamide, 3-[2-(dimethylamino)ethyl]-N-methyl-, butanedioate (1:1)
Common Name	Sumatriptan Succinate
CAS Number	103628-48-4
Impurities and/or Stabilizing Additives	No data available

	Section 4: First Aid Measures
General Advice	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.
If Inhaled	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
In Case of Skin Contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
In Case of Eye Contact	Rinse with water. Get medical attention if irritation develops and persists.
If Swallowed	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most Important Symptoms and Effects	Irritation of eyes and mucous membranes. May cause allergic skin reaction. May cause allergic respiratory reaction. Indication of immediate medical attention and special treatment needed Overdose treatment should be symptomatic and supportive and may include the following: Administer activated charcoal, if recent ingestion. For severe hypertension: Monitor vital signs regularly and administer nitroprusside, nitroglycerin, or phentolamine. For ventricular arrhythmia: Obtain an ECG, institute continuous cardiac monitoring, and administer oxygen. Administer lidocaine and amiodarone, or sotalol for monomorphic ventricular tachycardia (VT). Amiodarone and sotalol should generally not be used if QT prolongation or torsades de pointes is present. For serotonin syndrome: Administer benzodiazepines or cyproheptadine. Severe cases may be managed with benzodiazepine sedation and neuromuscular paralysis with non-depolarizing agents. Monitor for hypertension, ventricular dysrhythmias, and clinical evidence of ischemia. Cardiac monitoring as indicated. Evaluate pulse oximetry and/or ABGs in patients with chest pain or shortness or breath. Monitor symptomatic patients for acidosis/electrolyte disorders (particularly hypokalemia, hypocalcemia, and hypomagnesemia). [Drugdex 2008]

	Section 5: Fire Fighting Measures
Suitable Extinguishing Media	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2. Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use standard firefighting procedures and consider the hazards of other involved materials.
Special Hazards Arising From the Substance/Mixture	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
Special PPE and/or Precautions for Firefighters	Wear suitable protective equipment.

Section 6: Accidental Release Measures	
Personal Precautions, Protective Equipment and Emergency Procedures	Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and Materials Used for Containment	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.
Cleanup Procedures	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

Section 7: Handling and Storage		
Precautions for Safe Handling	Avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials. Combustible dust clouds may be created where operations produce fine material (dust). Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions.	
Conditions for Safe Storage	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.	

	Section 8: Exposure Controls/Personal Protection
Components with Workplace Control Parameters	Sumatripta n Succinate STEL 100 micrograms/m3 (15 minutes) (CAS 103628-48-4) TWA 50 micrograms/m3 Biological limit values No biological exposure limits noted for the ingredient(s).
Appropriate Engineering Controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Avoid any open handling of this material, particularly for grinding, crushing, weighing, or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.
PPE - Eye/Face Protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
PPE - Skin Protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.
PPE - Body Protection	For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent takehome contamination.
PPE - Respiratory Protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

	Section 9: Physical and Chemical Properties
Appearance	White or almost white powder. Physical state Solid. Form Powder.
Upper/Lower Flammability or Explosive Limits	Not available.
Odor	Not available.
Vapor Pressure	Not available.
Odor Threshold	Not available.
Vapor Density	Not available.
рН	4.5 - 5.3 (1% aqueous solution)
Relative Density	Not available.
Melting Point/Freezing Point	329 - 334.4 °F (165 - 168 °C)
Solubility	Solubility in water Freely soluble. Solubility (other) Sparingly soluble in methanol; practically insoluble in methylene chloride.
Initial Boiling Point and Boiling Range	Not available.
Flash Point	Not available.
Evaporation Rate	Not available.
Flammability (Solid, Gas)	Not applicable.
Partition Coefficient	Not available.
Auto-Ignition Temperature	788 °F (420 °C)
Decomposition Temperature	Not available.
Viscosity	Not available.

Section 10: Stability and Reactivity	
Reactivity	No reactivity hazards known.
Chemical Stability	Material is stable under normal conditions.
Possibility of Hazardous Reactions	No dangerous reaction known under conditions of normal use.
Conditions to Avoid	None known.
Incompatible Materials	Acids. Acid chlorides Acid anhydrides Strong oxidizing agents.
Hazardous Decomposition Products	NOx. SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

Section 11: Toxicological Information	
Acute Toxicity - LD50 Oral	LD50 Rat Oral > 2939 mg/kg
Acute Toxicity - Inhalation	No data available
Acute Toxicity - Dermal	No data available
Acute Toxicity - Eye	No data available
Skin Corrosion/Irritation	Due to lack of data the classification is not possible.
Serious Eye Damage/Irritation	Causes eye irritation.
Respiratory or Skin Sensitazation	May cause allergy or asthma symptoms or breathing difficulties if inhaled. Anaphylactic reactions following therapeutic use have been reported. May cause an allergic skin reaction. Allergic contact dermatitis has been reported.
Germ Cell Mutagenicity	Due to lack of data the classification is not possible.
Carcinogenicity IARC	Based on available data, the classification criteria are not met. A related material has not caused cancer in animal studies. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.
Carcinogenicity ACGIH	No data available
Carcinogenicity NTP	Based on available data, the classification criteria are not met. A related material has not caused cancer in animal studies. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.
Carcinogenicity OSHA	Based on available data, the classification criteria are not met. A related material has not caused cancer in animal studies. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.
Reproductive Toxicity	Based on available data, the classification criteria are not met. Reproductivity 1000 mg/kg/day Reproductivity study Result: Maternal toxicity and adverse fetal effects were observed. Species: Rabbit Reproductivity study Result: No evidence of embryolethality when administered through IV; oral administration was associated with increased incidence of fetal vascular and skeletal abnormalities. Species: Rabbit
Specific Target Organ Toxicity - Single Exposure	Based on available data, the classification criteria are not met.
Specific Target Organ Toxicity - Repeated Exposure	Based on available data, the classification criteria are not met.
Aspiration Hazard	Based on available data, the classification criteria are not met.

Section 12: Ecological Information	
Toxicity	Crustacea EC50 Daphnia pulex 290 mg/l, 48 hours Aquatic Fish EC50 Rainbow Trout > 100 mg/l, 96 hours
Persistence and Degradability	No data is available on the degradability of this product.
Bio-accumulative Potential	Not available.
Mobility in Soil	Not available.
Other Adverse Effects	Not available.

Section 13: Disposal Considerations	
Waste Treatment Methods Product	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Waste Treatment Methods Packaging	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information		
UN Number	Not dangerous goods.	
UN Proper Shipping Name	N/A	
Transport Hazard Class(es)	N/A	
Packaging Group	N/A	
Environmental Hazards	No data available.	

Section 15: Regulatory Information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable. One or more components are not listed on TSCA. Superfund Amendments and Reauthorization Act of 1986 (SARA) Hazard categories Immediate Hazard - No Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No SARA 302 Extremely hazardous substance No SARA 311/312 Hazardous chemical No Other federal regulations Safe Drinking Water Act (SDWA) Not regulated. Food and Drug Administration (FDA) Not regulated. US state regulations 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 No Substances (EINECS) 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 Yes Philippines Philippine Inventory of Chemicals and Chemical Substances No (PICCS) 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)

Section 16: Other Information		
Additional Information	N/A	
Prepared By	Scarlotte Smith	
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Disclaimer

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