

SAFETY DATA SHEET
Sumatriptan Injection



Caplin Steriles Limited

SECTION 1: IDENTIFICATION

Product Identifier	:	Sumatriptan Injection
Synonym(s)	:	Sumatriptan Injection USP 6 mg/0.5 mL
Product Use	:	Medicinal Product
Supplier Details	:	Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA.
Emergency Telephone Number	:	+91-4467901901/02/03

SECTION 2: HAZARDS 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.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Mixtures

Name	Common Name or	CAS Number	%
Sumatriptan Succinate	GR 43175C 3-(2-(DIMETHYLAMINO)ETHYL)-N-METHYL SUCCINATE 357 (GW ACN)	103628-48-4	1.1 - < 1.7
Other components below reportable levels			>98.0

SECTION 4: FIRST AID MEASURES

Inhalation	:	In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention immediately.
Skin Contact	:	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Remove and isolate contaminated clothing and shoes. Get medical attention immediately.
Eye Contact	:	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Ingestion	:	Rinse mouth. Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

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Most important symptoms/ effects, acute and delayed	: The following adverse effects have been noted with therapeutic use of this material: dizziness; drowsiness; abnormal nervous system sensations; difficult or irregular breathing; nausea; vomiting; feelings of heaviness or pressure; weakness; fatigue.
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 local poison control information centre.
General Information	: Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

SECTION 5: FIRE FIGHTING MEASURES

Suitable Extinguishing Media	: Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	: Not available.
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	: Move container from fire area if it can be done without risk.

SECTION 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 personal protective equipment. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the MSDS.
Methods and materials for containment and cleaning up	: Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent product from entering drains. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills in original containers for re-use. For waste disposal, see section 13 of the MSDS.
Environmental precautions	: Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

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SECTION 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. Avoid contact during pregnancy/while nursing. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Avoid release to the environment. Do not empty into drains.
Conditions for safe storage, including any incompatibilities	: Store locked up. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the MSDS).

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Occupational Exposure Limits

Compound	Type	Value	Note
Sumatriptan Succinate (CAS 103628-48-4)	15 MIN STEL 8HR TWA OHC	100 mcg/m ³ 50 mcg/m ³	REPRODUCTIVE HAZARD

Biological limit values	: No biological exposure limits noted for the ingredient(s)
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. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection	: Wear safety glasses with side shields (or goggles). Wear a full-face respirator, if needed.
Hand protection	: The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.
Other	: Not normally needed.
Respiratory protection	: No personal respiratory protective equipment normally required.
Thermal hazards	: Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	: When using, do not eat, drink or smoke. Wash hands after handling and before eating. An occupational/industrial hygiene monitoring method has

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	been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.
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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical State	:	Liquid
Form	:	Solution
Color	:	Clear, colorless to pale yellow solution
Odor	:	Not Available
Odor Threshold	:	Not Available
pH	:	4.2 – 5.3
Melting Point	:	Not Available
Boiling Point	:	Not Available
Flash Point	:	Not Available
Evaporation Rate	:	Not Available
Flammability	:	Not Available
Lower and Upper Explosive (flammable) limits	:	Not Available
Vapour Pressure	:	Not Available
Vapor Density	:	Not Available
Relative Density	:	Not Available
Solubility	:	Approx. 164 mg/mL in water
Partition Coefficient: n-octanol/water	:	Not Available
Auto Ignition Temperature	:	Not Available
Decomposition Temperature	:	Not Available
Viscosity	:	Not Available

SECTION 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 is known under conditions of normal use.
Conditions to Avoid	:	Contact with incompatible material.
Incompatible Materials	:	Strong oxidizing agents.
Hazardous Decomposition Products	:	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

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SECTION 11: TOXICOLOGICAL INFORMATION

Information on likely routes of exposure		
Ingestion	:	May be harmful if swallowed.
Inhalation	:	Health injuries are not known or expected under normal use.
Skin Contact	:	Health injuries are not known or expected under normal use
Eye Contact	:	Health injuries are not known or expected under normal use.
Symptoms related to the physical, chemical and toxicological characteristics	:	The following adverse effects have been noted with therapeutic use of this material: dizziness; drowsiness; abnormal nervous system sensations; difficult or irregular breathing; nausea; vomiting; feelings of heaviness or pressure; weakness; fatigue.

Information on toxicological effects

Acute Toxicity May be harmful if swallowed.

Components	Species	Test Results
SUMATRIPTAN SUCCINATE (CAS 103628-48-4)		
Acute Oral (LD50)	Mouse Rat	>1500 mg/kg >2000 mg/kg
Chronic Oral NOAEL TD	Rat Rat	5 mg/kg/day, 18 months >= 50 mg/kg/day
Subchronic Oral TD	Dog	<= 50 mg/kg/day, 60 weeks

Skin corrosion/irritation	:	Health injuries are not known or expected under normal use.
Serious eye damage/eye irritation	:	Health injuries are not known or expected under normal use.
Eye Sumatriptan Succinate	:	OECD 405 Result: Mild irritant Species: Rabbit
Respiratory Sensitization	:	Not established.
Skin Sensitization	:	This product is not expected to cause skin sensitization.
Sensitization 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.
Sumatriptan Succinate	:	<= 1000 mg/kg Micronucleus Test Result: Negative Species: Rat

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		Ames, GLP Result: Negative Bacterial Fluctuation Test Result: Negative Chromosomal Aberration Assay In Vitro, GLP Result: Negative HPRT gene mutation in human lymphocytes Result: Negative WHO Nitrosation Assay Result: Negative Yeast Mutation Assay Result: Negative
Carcinogenicity	:	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
Sumatriptan Succinate		10 - 160 mg/kg/day Result: Negative Species: Mouse 10 - 160 mg/kg/day Result: Negative Species: Rat
Reproductive Toxicity	:	Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.
Sumatriptan Succinate		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 >= 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
Specific target organ toxicity - single exposure	:	Circulation system.
Specific target organ toxicity - repeated exposure	:	None Known
Aspiration hazard	:	Due to partial or complete lack of data the classification is not possible.
Chronic effects	:	Prolonged exposure may cause chronic effects.
Further information	:	None Known.

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SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity	:	Contains a substance which causes risk of hazardous effects to the environment.
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Components	Species	Test Results
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
Algae 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
Crustacea NOEC	Water flea (Daphnia pulex)	200 mg/l, 48 hours
Fish EC50	Rainbow trout (Juvenile Oncorhyncus mykiss)	> 100 mg/l, 96 hours, OECD 203
Fish 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
Crustacea NOEC	Daphnia	32 mg/l, 8 days

Persistence and degradability	
Photolysis	
UV/visible spectrum wavelength	:
SUMATRIPTAN SUCCINATE	290 nm
Hydrolysis	
Half-life (Hydrolysis-neutral)	:
SUMATRIPTAN SUCCINATE	> 1 Years Measured
Biodegradability	
Percent degradation (Aerobic biodegradation-soil)	:
SUMATRIPTAN SUCCINATE	32 - 40 %, 64 days, Soil
Bioaccumulative potential	
Partition coefficient n-octanol / water (log Kow)	:
SUMATRIPTAN SUCCINATE	0.93 (Measured)
Mobility in soil	
Adsorption	
Soil/sediment sorption - log Koc	:
	3.52 - 3.57 Measured

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SUMATRIPTAN SUCCINATE	
Other adverse effects	: Not available

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal Instructions	:	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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	:	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.

SECTION 14: TRANSPORT INFORMATION

DOT	IMDG	IATA
Not regulated as a dangerous good	Not regulated as a dangerous good	Not regulated as a dangerous good
Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.	

SECTION 15: REGULATORY INFORMATION

US federal regulations	:	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)	:	Not regulated.
CERCLA Hazardous Substance List (40 CFR 302.4)	:	Not listed.
US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	:	Not listed.
SARA 304 Emergency release notification	:	Not regulated.
Superfund Amendments and Reauthorization Act of 1986 (SARA)		

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Hazard categories	:	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard – No
SARA 302 Extremely hazardous substance	:	No
SARA 311/312 Hazardous chemical	:	No

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
Food and Drug Administration (FDA)	:	Not regulated

US State Regulations

US. Massachusetts RTK - Substance List	:	Not regulated
US. New Jersey Worker and Community Right-to-Know Act	:	Not regulated
US. Pennsylvania RTK - Hazardous Substances	:	Not regulated
US. Rhode Island RTK	:	Not regulated
US. California Proposition 65	:	California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory Name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates all the 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).

SECTION 16: OTHER INFORMATION

History:

Issued Date	:	20.07.21
Revision Date	:	Nil
Version	:	00

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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.

----End of SDS---