

1. Identification

Product identifier Sumatriptan Injection USP

Other means of identification

SDS number 55150-173

Recommended use Pharmaceutical applications.

Recommended restrictions None known.

Manufacturer / Importer / Supplier / Distributor information

Company name AuroMedics Pharma
Address 6 Wheeling Road, Dayton NJ 08810
 US
Telephone 1-888-238-7880
E-mail AuroMedicsCS@aurobindousa.com
Contact person Vincent P. Andolina
Emergency phone number 1-888-238-7880

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word Not available.

Hazard statement Not available.

Precautionary statement

Prevention Observe good industrial hygiene practices.

Response Wash thoroughly after handling.

Storage Store away from incompatible materials.

Disposal Dispose of waste and residues in accordance with local authority requirements.

Hazard(s) not otherwise classified (HNOC) Not classified.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Sumatriptan succinate	103628-48-4	1-2

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Wash contact areas with soap and water.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth thoroughly. No harmful effects expected in amounts likely to be ingested by accident.

Most important symptoms/effects, acute and delayed Dry skin.

Indication of immediate medical attention and special treatment needed Treat symptomatically.

General information Get medical attention if any discomfort continues.

5. Fire-fighting measures

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	None known.
Special protective equipment and precautions for firefighters	Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace.
Fire-fighting equipment/instructions	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Avoid prolonged and repeated contact. Wear suitable protective clothing. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Absorb spillage with suitable absorbent material.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Avoid prolonged and repeated contact. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Keep container closed.

8. Exposure controls/personal protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	No special requirements under ordinary conditions of use and with adequate ventilation.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Risk of splashes: Wear approved safety glasses or goggles.
Skin protection	
Hand protection	Not normally needed.
Other	No protection is ordinarily required under normal conditions of use.
Respiratory protection	No protection is ordinarily required under normal conditions of use.
Thermal hazards	None.
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.

9. Physical and chemical properties

Appearance	Clear liquid.
Physical state	Liquid.
Form	Liquid.
Color	Colorless to pale yellow.
Odor	Not available.
Odor threshold	Not available.
pH	4.2 - 5.3
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not applicable.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.

Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not applicable.
Explosive limit - upper (%)	Not applicable.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	1.007 Approx.
Relative density temperature	68 °F (20 °C)
Solubility(ies)	Soluble in water.
Partition coefficient (n-octanol/water)	12 @ pH 10.7
Auto-ignition temperature	Not applicable.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
VOC (Weight %)	0 Test Method: Product Formulation Data

10. Stability and reactivity

Reactivity	The product is stable and non reactive under normal conditions of use, storage and transport.
Chemical stability	Stable under the prescribed storage conditions.
Possibility of hazardous reactions	None known.
Conditions to avoid	Excessive heat. Freezing. Sunlight.
Incompatible materials	None known.
Hazardous decomposition products	None known.

11. Toxicological information

Information on likely routes of exposure

Ingestion	No harmful effects expected in amounts likely to be ingested by accident.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Prolonged contact may cause dryness of the skin.
Eye contact	Direct contact with eyes may cause temporary irritation.
Symptoms related to the physical, chemical and toxicological characteristics	Dry skin.

Information on toxicological effects

Acute toxicity	No data available.
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Components	Species	Test Results
Sumatriptan succinate (CAS 103628-48-4)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2939 mg/kg
Skin corrosion/irritation	No data available.	
Serious eye damage/eye irritation	No data available.	
Respiratory sensitization	No data available.	
Skin sensitization	No data available.	
Germ cell mutagenicity	No data available.	
Carcinogenicity	No data available.	
Reproductive toxicity	No data available.	
Specific target organ toxicity - single exposure	No data available.	

Specific target organ toxicity - repeated exposure No data available.

Aspiration hazard No data available.

12. Ecological information

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

Persistence and degradability No data available.

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

Sumatriptan Injection USP (CAS Mixture) 12, @ pH 10.7

Mobility in soil Not available.

Mobility in general The product is water soluble and may spread in water systems.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Do not discharge into drains, water courses or onto the ground.

Local disposal regulations Dispose of in accordance with local regulations.

Hazardous waste code Not regulated.

Waste from residues / unused products Dispose of in accordance with local regulations.

Contaminated packaging Since emptied containers retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

IMDG

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations This product is hazardous according to OSHA 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes

Delayed Hazard - No

Fire Hazard - No

Pressure Hazard - No

Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical Yes

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

This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

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

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Not listed.

International Inventories

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

*A "Yes" indicates this product complies 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 05-16-2013

Revision date -

Version # 01

Disclaimer This information is provided without warranty. The information is believed to be correct. This information should be used to make an independent determination of the methods to safeguard workers and the environment.