



# SAFETY DATA SHEET

## 1. Identification

Product identifier	Rizatriptan Benzoate System Suitability Mixture	
Other means of identification		
Catalog number	1604891	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Serious eye damage/eye irritation	Category 2A
OSHA hazard(s)	Not classified.	
Label elements		



Signal word	Warning	
Hazard statement	Causes serious eye irritation.	
Precautionary statement		
Prevention	Wash with soap and water thoroughly after handling. Wear eye/face protection.	
Response	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.	
Storage	Not available.	
Disposal	Not available.	
Hazard(s) not otherwise classified (HNOC)	Not classified.	

## 3. Composition/information on ingredients

### Mixture

#### Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Rizatriptan Benzoate		145202-66-0	99

#### Non-hazardous components

Chemical name	Common name and synonyms	CAS number	%
Rizatriptan Impurity C		Unknown	1

## 4. First-aid measures

<b>Inhalation</b>	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Get medical attention if irritation develops and persists. Wash off immediately with plenty of water. Wash off with soap and water. Rinse skin with water/shower. Take off contaminated clothing and wash before reuse.
<b>Eye contact</b>	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth thoroughly. Do not induce vomiting without advice from poison control center. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Most important symptoms/effects, acute and delayed</b>	Irritation of eyes and mucous membranes.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically.
<b>General information</b>	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.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No unusual fire or explosion hazards noted.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire-fighting equipment/instructions</b>	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
<b>Specific methods</b>	Cool containers exposed to flames with water until well after the fire is out.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	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.
<b>Methods and materials for containment and cleaning up</b>	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. Wash spill site.

## 7. Handling and storage

<b>Precautions for safe handling</b>	As a general rule, when handling USP Reference Standards, 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.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Exposure guidelines</b>	No exposure standards allocated.
<b>Appropriate engineering controls</b>	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.

## Individual protection measures, such as personal protective equipment

<b>Eye/face protection</b>	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.
<b>Skin protection</b>	
<b>Hand protection</b>	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.
<b>Other</b>	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
<b>Respiratory protection</b>	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).
<b>Thermal hazards</b>	Not available.
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

<b>Appearance</b>	Solid.
<b>Physical state</b>	Solid.
<b>Form</b>	Powder.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not applicable.
<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 in 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.

## 10. Stability and reactivity

<b>Reactivity</b>	No reactivity hazards known.
<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>	None known.
<b>Incompatible materials</b>	None known.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx

## 11. Toxicological information

### Information on likely routes of exposure

<b>Ingestion</b>	Based on available data, the classification criteria are not met.
<b>Inhalation</b>	Due to lack of data the classification is not possible.
<b>Skin contact</b>	Based on available data, the classification criteria are not met.

<b>Eye contact</b>	Causes serious eye irritation.	
<b>Symptoms related to the physical, chemical, and toxicological characteristics</b>	Dizziness. Nausea. Vomiting. Headache. Burning or tingling sensations. Fatigue. Drowsiness. Dry mouth. Heaviness, tightness, or pressure in chest or neck. Speech disturbances. Weakness. Pounding heartbeat. Irregular heartbeat. Difficulty breathing. Weakness or numbness of arm or leg.	
<b>Medical conditions aggravated by exposure</b>	Cardiovascular disease. Hypertension. Impaired kidney function. Impaired liver function.	
<b>Acute toxicity</b>		
<b>Components</b>	<b>Species</b>	<b>Test Results</b>
Rizatriptan Benzoate (CAS 145202-66-0)		
<i>Oral</i>		
LD50	Mouse	700 mg/kg
	Rat	2227 mg/kg
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.	
<b>Serious eye damage/eye irritation</b>	Causes serious eye irritation.	
<b>Local effects</b>		
Rizatriptan Benzoate	Bovine corneal opacity and permeability assay Result: Irritant Organ: Eye Severity: Moderate Irritancy Result: Negative Species: Rabbit Organ: Skin	
<b>Respiratory sensitization</b>	Due to lack of data the classification is not possible.	
<b>Skin sensitization</b>	Due to lack of data the classification is not possible.	
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.	
<b>Mutagenicity</b>		
Rizatriptan Benzoate	Ames test Result: Negative with and without activation In vitro alkaline elution assay (rat hepatocytes) Result: Negative In vitro mammalian cell mutagenesis assay (V-79 Chinese hamster lung cells) Result: Negative In vivo chromosomal aberration assay (mouse bone marrow) Result: Negative	
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
Rizatriptan Benzoate	< 125 mg/kg/day 100-Week study (oral gavage) Result: No increase in tumors Species: Mouse < 125 mg/kg/day 105-Week study (oral gavage) Result: No increase in tumors Species: Rat	
<b>Reproductive toxicity</b>	Based on available data, the classification criteria are not met.	
<b>Reproductivity</b>		
Rizatriptan Benzoate	100 - 250 mg/kg/day Pre- and Post-natal developmental study Result: Increased pup mortality at birth, decreased weight gain persisting into adulthood, decreased learning capacity in offspring Species: Rat 100 mg/kg/day Embryofetal development study Result: No developmental effects; decreased maternal and fetal weight gain Species: Rat 50 mg/kg/day Embryogetal development study Result: No developmental effect; decreased maternal and fetal weight gain Species: Rabbit	
<b>Specific target organ toxicity - single exposure</b>	Due to lack of data the classification is not possible.	
<b>Specific target organ toxicity - repeated exposure</b>	Due to lack of data the classification is not possible.	

**Aspiration hazard** Based on available data, the classification criteria are not met.

## 12. Ecological information

**Ecotoxicity** There are no data on the ecotoxicity of this product.  
**Persistence and degradability** No data is available on the degradability of this product.  
**Bioaccumulative potential** Not available.  
**Mobility in soil** Not available.  
**Other adverse effects** Not available.

## 13. Disposal considerations

**Disposal instructions** This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). 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. Dispose of contents/container in accordance with local/regional/national/international regulations.

**Local disposal regulations** Not available.

**Hazardous waste code** Not regulated.

**Waste from residues / unused products** 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.

## 14. Transport information

### DOT

Not regulated as a hazardous material by DOT.

### IATA

Not regulated as a dangerous good.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** No information available.

## 15. Regulatory information

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.  
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** This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm. 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

Country(s) or region	Inventory name	On inventory (yes/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)

## 16. Other information, including date of preparation or last revision

<b>Issue date</b>	01-16-2013
<b>Version #</b>	01
<b>Further information</b>	Not available.
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