



# SAFETY DATA SHEET

## 1. Identification

Product identifier	Frovatriptan Succinate		
Other means of identification			
Catalog number	1286413		
CAS number	158930-17-7		
Chemical name	(+)-(R)-5,6,7,8-Tetrahydro-6-(methylamino)carbazole-3-carboxamide succinate (1:1), monohydrate		
Recommended use	For analytical laboratory use only.		
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.		
Manufacturer/Importer/Supplier/Distributor information			
Manufacturer			
Company name	U. S. Pharmacopeia		
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States		
Telephone	Customer Service	301-881-0666	
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	Specific target organ toxicity, single exposure Category 1 (cardiovascular system)
Environmental hazards	Not classified.
OSHA defined hazards	Not classified.

### Label elements



Signal word	Danger
Hazard statement	Causes damage to organs (cardiovascular system).
Precautionary statement	
Prevention	Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling.
Response	If exposed: Call a poison center/doctor.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Potent pharmacologically active material.

## 3. Composition/information on ingredients

### Substance

Chemical name	Common name and synonyms	CAS number	%
Frovatriptan Succinate		158930-17-7	100

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

## 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. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Most important symptoms/effects, acute and delayed</b>	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
<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. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding 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>	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.
<b>Specific methods</b>	Cool containers exposed to flames with water until well after the fire is out.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	As a general rule, when handling USP materials, 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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

## 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.

**Exposure limit values****Industrial Use  
Material****Type****Value**Frovatriptan Succinate  
(CAS 158930-17-7)

TWA

0.05 mg/m3

**Biological limit values**

No biological exposure limits noted for the ingredient(s).

**Appropriate engineering  
controls**

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

**Individual protection measures, such as personal protective equipment****Eye/face protection**

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

**Skin protection****Hand protection**

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

**Other**

Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

**Respiratory protection**

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

**Thermal hazards**

Wear appropriate thermal protective clothing, when necessary.

**General hygiene  
considerations**

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of USP materials.

**9. Physical and chemical properties****Appearance**

Appearance descriptions are general information and not specific to any USP lot.

**Physical state**

Solid.

**Form**

Powder.

**Color**

White. Off-white.

**Odor**

Not available.

**Odor threshold**

Not available.

**pH**

Not available.

**Melting point/freezing point**

329 - 341.6 °F (165 - 172 °C)

**Initial boiling point and boiling  
range**

Not available.

**Flash point**

Not available.

**Evaporation rate**

Not available.

**Flammability (solid, gas)**

Not available.

**Upper/lower flammability or explosive limits****Flammability limit - lower  
(%)**

Not available.

**Flammability limit - upper  
(%)**

Not available.

**Explosive limit - lower (%)**

Not available.

**Explosive limit - upper (%)**

Not available.

**Vapor pressure**

Not available.

**Vapor density**

Not available.

**Relative density**

Not available.

**Solubility(ies)****Solubility (water)**

Soluble.

<b>Solubility (other)</b>	Methanol: Slightly soluble. Ethanol: Slightly soluble. Dichloromethane: Practically insoluble. Ethyl acetate: Practically insoluble. Acetone: Practically insoluble. Hexane: Practically insoluble.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

#### Other information

<b>Chemical family</b>	Indole derivative.
<b>Molecular formula</b>	C <sub>14</sub> H <sub>17</sub> N <sub>3</sub> O·C <sub>4</sub> H <sub>6</sub> O <sub>4</sub> ·H <sub>2</sub> O
<b>Molecular weight</b>	379.41
<b>pH in aqueous solution</b>	4.9 (Solution: 1%)

## 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>	Stable at 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. Strong bases.
<b>Hazardous decomposition products</b>	NO <sub>x</sub> . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

#### Information on likely routes of exposure

<b>Inhalation</b>	Knowledge about health hazard is incomplete.
<b>Skin contact</b>	Knowledge about health hazard is incomplete.
<b>Eye contact</b>	Knowledge about health hazard is incomplete.
<b>Ingestion</b>	Based on information from therapeutic use, this material may cause: Cardiovascular effects.

<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	Triptans: Dizziness. Weakness. Fatigue. Gastrointestinal disturbances. Sensory disturbances. Heaviness, tightness, or pressure in chest, neck or jaw. Serotonin syndrome (agitation, incoordination, mood or mental changes, irregular heartbeat, hallucinations).
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#### Information on toxicological effects

##### Acute toxicity

Product	Species	Test Results
Frovatriptan Succinate (CAS 158930-17-7)		
<u><b>Acute</b></u>		
<b>Oral</b>		
LD50	Mouse	> 2000 mg/kg

<b>Skin corrosion/irritation</b>	Knowledge about health hazard is incomplete.
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<b>Serious eye damage/eye irritation</b>	Knowledge about health hazard is incomplete.
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#### Respiratory or skin sensitization

<b>Respiratory sensitization</b>	Knowledge about health hazard is incomplete.
<b>Skin sensitization</b>	Knowledge about health hazard is incomplete.

<b>Germ cell mutagenicity</b>	Knowledge about mutagenicity is incomplete.
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#### Mutagenicity

Ames test  
Result: Equivocal.  
Ex vivo unscheduled DNA synthesis assay in rat liver  
Result: Negative.  
In vitro mouse bone marrow micronucleus test  
Result: Negative.

### **Mutagenicity**

In vitro mouse lymphoma assay

Result: Negative.

In vitro study with human lymphocytes

Result: Clastogenic without activation; not clastogenic with activation.

### **Carcinogenicity**

Knowledge about carcinogenicity is incomplete.

20 - 400 mg/kg/day Carcinogenicity study

Result: Increased incidence of sarcomas (not relevant to humans)

Species: Mouse

Test Duration: 26 weeks

### **IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

### **OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)**

Not listed.

### **US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

### **Reproductive toxicity**

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

#### **Reproductivity**

100 - 1000 mg/kg/day Reproductivity and development study, oral doses.

Result: No adverse effects on fertility; dose-related increases in renal defects and skeletal variations.

Species: Rat

5 - 80 mg/kg/day Reproductivity and development study

Result: No adverse effects on fetal development.

Species: Rabbit

### **Specific target organ toxicity - single exposure**

Causes damage to organs (cardiovascular system).

### **Specific target organ toxicity - repeated exposure**

Knowledge about health hazard is incomplete.

### **Aspiration hazard**

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

### **Further information**

Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

## **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 is available on the degradability of this product.

### **Bioaccumulative potential**

No data available.

### **Mobility in soil**

No data available.

### **Other adverse effects**

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## **13. Disposal considerations**

### **Disposal instructions**

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.

### **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**

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**

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 dangerous goods.

### IATA

Not regulated as dangerous goods.

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

**General information** It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

## 15. Regulatory information

**US federal regulations** CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.  
This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

### Toxic Substances Control Act (TSCA)

#### 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 1910.1001-1053)

Not listed.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### SARA 302 Extremely hazardous substance

Not listed.

**SARA 311/312 Hazardous chemical** Yes

**Classified hazard categories** Specific target organ toxicity (single or repeated exposure)

#### 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** 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 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

Country(s) or region	Inventory name	On inventory (yes/no)*
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
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

<b>Issue date</b>	12-07-2012
<b>Revision date</b>	12-07-2023
<b>Version #</b>	02
<b>Disclaimer</b>	<p>USP materials are sold for analytical laboratory use only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used for analytical laboratory use and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP materials are intended for use by persons having technical skill and at their own discretion and risk. This information has been compiled by USP staff from sources considered to be scientifically reliable but has not been independently verified by USP. USP does not guarantee the accuracy or completeness of the information from these sources included herein nor should the statements contained herein be considered an official expression by USP. USP does not independently create or develop the information included in this safety data sheet. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.</p>