# U.S. Pharmacopeial Convention

# SAFETY DATA SHEET

### 1. Identification

Product identifier Eletriptan Hydrobromide

Other means of identification

 Catalog number
 1234453

 CAS number
 273211-28-2

Chemical name 3-[[(R)-1-Methyl-2-pyrrolidinyl]methyl]-5-[2-(phenylsulfonyl)ethyl]indole monohydrobromide

monohydrate

**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

Manufacturer

Company nameU. S. PharmacopeiaAddress12601 Twinbrook Parkway

Rockville MD 20852-179

20852-1790 United States

**Telephone** RS Technical Services 301-816-8129

Website www.usp.org
E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Acute toxicity, oral Category 4

Acute toxicity, dermal Category 4
Serious eye damage/eye irritation Category 1

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Harmful if swallowed. Harmful in contact with skin. Causes serious eye damage.

**Precautionary statement** 

**Prevention** Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face

protection.

Response If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If on skin: Wash with

plenty of water. Call a poison center/doctor if you feel unwell. Take off contaminated clothing and wash before reuse. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor.

Storage Not available.

**Disposal** Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise

classified (HNOC)

None known.

**Supplemental information** Pharmacologically active material.

3. Composition/information on ingredients

Substance

Material name: Eletriptan Hydrobromide

USP SDS US

CAS number **Chemical name** Common name and synonyms % Eletriptan Hydrobromide 273211-28-2 100

### 4. First-aid measures

If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Inhalation

Call a physician if symptoms develop or persist.

Rinse skin with water/shower. Get medical attention if irritation develops and persists. Wash Skin contact

contaminated clothing before reuse.

Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if Eye contact

present and easy to do. Continue rinsing. Get medical attention immediately.

Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Ingestion

Get medical advice/attention if you feel unwell.

Most important

symptoms/effects, acute and

delayed

Pharmacologically active material. Occupational exposure may cause physiological effects.

Indication of immediate medical attention and special

Provide general supportive measures and treat symptomatically.

treatment needed **General information** 

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

Suitable extinguishing media Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding

materials.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters Wear suitable protective equipment.

Fire fighting

equipment/instructions

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. Specific methods

General fire hazards No unusual fire or explosion hazards noted.

### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

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.

Methods and materials for containment and cleaning up

For waste disposal, see section 13 of the SDS. 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.

**Environmental precautions** 

Avoid discharge into drains, water courses or onto the ground.

### 7. Handling and storage

Precautions for safe handling

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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities

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

# 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.

Material name: Eletriptan Hydrobromide

### **Exposure limit values**

Industrial Use

**Form** Material Value Type Eletriptan Hydrobromide **TWA** 0.1 mg/m3 anhydrous (CAS 273211-28-2)

**Biological limit values** 

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

Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. 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

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Eye/face protection

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** 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.

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of Other

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.

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face Respiratory protection

respirator with HEPA filters for spill cleanup. Chose 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

Handling practices in this SDS are recommendations for laboratory use of reference standards.

Procedures for any other uses or quantities should be determined after an appropriate

assessment.

# 9. Physical and chemical properties

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

Solid. Physical state Powder. **Form** 

Color Off-white. Light brown.

Odor Odorless. **Odor threshold** Not available. Not available. рΗ Not available. Melting point/freezing point

Initial boiling point and boiling

range

Not available.

Flash point Not available. **Evaporation rate** Not available. Not available. Flammability (solid, gas) Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

Not available.

Explosive limit - lower (%) Not available. Not available. Explosive limit - upper (%) Not available. Vapor pressure Vapor density Not available. Not available. Relative density

Solubility(ies)

Not available. Solubility (water)

Methanol: Freely soluble. Solubility (other)

Not available **Auto-ignition temperature** Not available. **Decomposition temperature** Not available. Viscosity

Other information

C22H26N2O2S . HBr . H2O Molecular formula

481.45 Molecular weight

# 10. Stability and reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport. Reactivity

Material is stable under normal conditions. **Chemical stability** 

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Incompatible materials None known. Hazardous decomposition

products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. SOx. HBr.

# 11. Toxicological information

### Information on likely routes of exposure

Inhalation Knowledge about health hazard is incomplete.

Harmful if swallowed.

Skin contact Harmful in contact with skin. Causes serious eye damage. Eye contact

Symptoms related to the physical, chemical, and

toxicological characteristics

Ingestion

Triptans: Dizziness. Weakness. Fatique. Gastrointestinal disturbances. Sensory disturbances. Heaviness, tightness, or pressure in chest, neck or jaw. Serotonin syndrome (agitation,

incoordination, mood or mental changes, irregular heartbeat, hallucinations).

### Information on toxicological effects

Harmful in contact with skin. Harmful if swallowed. Acute toxicity

Based on available data, the classification criteria are not met. Skin corrosion/irritation

Serious eye damage/eye

irritation

Causes serious eye damage.

### Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete.

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

Knowledge about mutagenicity is incomplete. Germ cell mutagenicity Knowledge about carcinogenicity is incomplete. Carcinogenicity

### IARC Monographs. Overall Evaluation of Carcinogenicity

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

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

Not listed

Reproductive toxicity Knowledge about health hazard is incomplete. Knowledge about health hazard is incomplete. Specific target organ toxicity -

single exposure

Specific target organ toxicity -

repeated exposure

Knowledge about health hazard is incomplete.

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

Pharmacologically active material. Occupational exposure may cause physiological effects. **Further information** 

## 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.

No data is available on the degradability of this product. Persistence and degradability

**Bioaccumulative potential** No data available. No data available. Mobility in soil

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.

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## 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).

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

emptied.

# 14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to

Not applicable.

Annex II of MARPOL 73/78 and the IBC Code

**General information** 

It is the shipper's responsibility to determine the correct transport classification at the time of

shipment.

## 15. Regulatory information

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication **US federal regulations** 

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.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

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

Not listed.

SARA 311/312 Hazardous

Yes

chemical

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)

Canada

Not regulated.

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material **US state regulations** 

is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**International Inventories** 

Country(s) or region On inventory (yes/no)\* Inventory name

Australia Australian Inventory of Chemical Substances (AICS)

Domestic Substances List (DSL) Nο

Canada Non-Domestic Substances List (NDSL)

No

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Nο

| 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                     |

<sup>\*</sup>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

 Issue date
 12-05-2016

 Revision date
 03-06-2018

Version # 02

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