SAFETY DATA SHEET



1. Identification

Product identifier Zolmitriptan

Other means of identification

Catalog number 1727009 139264-17-8 **CAS** number

Chemical name (S)-4-[[3-[2-(Dimethylamino)ethyl]indol-5-yl]methyl]-2-oxazolidinone

Recommended use Specified quality tests and assay use only.

Not for use as a drug. Not for administration to humans or animals. Recommended restrictions

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name U. S. Pharmacopeia **Address** 12601 Twinbrook Parkway

> Rockville MD

20852-1790 **United States**

RS Technical Services 301-816-8129 Telephone

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

CHEMTREC within US & 1-800-424-9300

Emergency phone number

Canada CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Acute toxicity, oral Category 4

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 Harmful if swallowed. Causes damage to organs (cardiovascular system).

Precautionary statement

Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Prevention

If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If exposed: Call a poison Response

center/doctor.

Store locked up. **Storage**

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

Hazard(s) not otherwise

This product is supplied in a small quantity which does not constitute a combustible dust hazard. classified (HNOC) The physical properties of this material indicate that in large quantities accumulated dust may be

hazardous.

Supplemental information Potent pharmacologically active material.

3. Composition/information on ingredients

Substance

Material name: Zolmitriptan USP SDS US

1727009 Version #: 04 Revision date: 02-06-2020 Issue date: 08-31-2011

Chemical nameCommon name and synonymsCAS number%Zolmitriptan139264-17-8100

4. First-aid measures

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

Do not use mouth-to-mouth method if the substance is inhaled. Call a physician if symptoms

develop or persist.

Skin contact Immediately flush skin with plenty of water. Get medical attention if irritation develops and persists.

Remove and isolate contaminated clothing and shoes. Wash clothing separately before reuse.

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

Ingestion

If ingestion of a large amount does occur, call a poison control center immediately. Rinse mouth.

Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if

substance is ingested. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Get medical advice/attention if you feel

ınwell.

Most important symptoms/effects, acute and delayed

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

Indication of immediate medical attention and special treatment needed

Treat symptomatically. Administer activated charcoal as a slurry. For severe hypertension, nitroprusside is preferred; labetalol, nitroglycerin, and phentolamine are alternatives. For ventricular arrhythmia, obtain ECG, institute continuous cardiac monitoring, and administer oxygen. For monomorphic ventricular tachycardia, administer lidocaine and amiodarone or sotalol. Amiodarone and sotalol should generally not be used if QT prolongation or torsades de pointes is present. For serotonin syndrome, administer benzodiazepines or cyproheptadine. Monitor blood pressure. Monitor arterial blood gas or pulse oximetry. Monitor cardiac rhythm. Monitor blood counts. Monitor acid-base status. Monitor electrolyte balance.

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

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and

in the presence of an ignition source is a potential dust explosion hazard.

Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

Fire fighting

equipment/instructions

Specific methods Use s

General fire hazards No unusual fire or explosion hazards noted.

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.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Wear appropriate protective equipment and clothing during clean-up. 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

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.

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. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). 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

Exposure limit values

Industrial Use Material	Туре	Value	
Zolmitriptan (CAS 139264-17-8)	STEL	0.1 mg/m3	
·	TWA	0.01 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.

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 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.

Physical stateSolid.FormPowder.ColorWhite.

Odor Not available.
Odor threshold Not available.
pH Not available.

Melting point/freezing point 266 - 285.8 °F (130 - 141 °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 Solubility(ies)

Solubility (water) Slightly soluble.

Solubility (other) Dichloromethane: Sparingly soluble.

Methanol: Soluble.

Not available.

Toluene: Practically insoluble.

Partition coefficient (n-octanol/water)

-1.34

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Chemical family Oxazolidinone.

Molecular formula C16H21N3O2

Molecular weight 287.36

pH in aqueous solution 8 - 9

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 known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Incompatible materials Alkalies.

Hazardous decomposition

products

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

11. Toxicological information

Information on likely routes of exposure

InhalationKnowledge about health hazard is incomplete.Skin contactKnowledge about health hazard is incomplete.Eye contactKnowledge about health hazard is incomplete.

Ingestion Harmful if swallowed.

Symptoms related to the physical, chemical, and

toxicological characteristics

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).

Information on toxicological effects

Acute toxicity Harmful if swallowed.

Product Species Test Results

Zolmitriptan (CAS 139264-17-8)

Oral

Rat 1000 mg/kg

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye Knowledge about health hazard is incomplete.

irritation

Respiratory or skin sensitization

Respiratory sensitization
Skin sensitization
Knowledge about health hazard is incomplete.
Knowledge about health hazard is incomplete.
Knowledge about mutagenicity is incomplete.

Mutagenicity

Ames test (Salmonella typhimurium) Result: Positive: With activation.

In vitro micronucleus assay (human lymphocytes)

Result: Positive.

In vivo mouse micronucleus test

Result: Negative.

Mutagenicity, In vitro mammalian gene cell mutation assay

(CHO/HGPRT) Result: Negative.

Mutagenicity, Unscheduled DNA synthesis test

Result: Negative.

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

400 mg/kg/day Carcinogenicity Result: No effect on tumor incidence.

Species: Mouse Test Duration: 85 weeks 400 mg/kg/day Carcinogenicity

Result: No effect on tumor incidence. A slight increase in the incidence of thyroid follicular cell hyperplasia and thyroid

follicular cell adenomas occurred in male rats.

Species: Rat

Test Duration: 86 weeks

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Knowledge about health hazard is incomplete.

Reproductivity

100 - 1200 mg/kg/day Reproductivity

Result: Dose-related increase in embryolethality.

Species: Rat

30 mg/kg/day Reproductivity

Result: Increase in embryolethality and maternal toxicity. Increased incidence of fetal malformations and variations.

Species: Rabbit

400 mg/kg/day Reproductivity

Result: Increased incidence of hydronephrosis and maternal

toxicity. No evidence of impaired fertility.

Species: Rat

Specific target organ toxicity -

Causes damage to organs (cardiovascular system).

Specific target organ toxicity -

repeated exposure

single 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.

Material name: Zolmitriptan USP SDS US

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 substance.

Bioaccumulative potential

Octanol/water partition coefficient log Kow

-1.34

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.

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

General information

Not applicable.

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

shipment.

15. Regulatory information

US federal regulationsThis 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.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

chemical

Yes

Classified hazard Combustible dust

categories Acute toxicity (any route of exposure)

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

Not regulated.

Inventory name

(SDWA)

Taiwan

US state regulations

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region

Australia Australian Inventory of Cher	nical Substances (AICS) No
Canada Domestic Substances List (OSL) No
Canada Non-Domestic Substances	.ist (NDSL)
China Inventory of Existing Chemi	cal Substances in China (IECSC)
Europe European Inventory of Exist Substances (EINECS)	ng Commercial Chemical No
European List of Notified Ch	emical Substances (ELINCS) No
Japan Inventory of Existing and Ne	w Chemical Substances (ENCS)
Korea Existing Chemicals List (EC	_) No
New Zealand Inventory	No
Philippines Philippine Inventory of Cher (PICCS)	nicals and Chemical Substances 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

Issue date 08-31-2011 **Revision date** 02-06-2020

Version # 04

United States & Puerto Rico

Further information Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the

Taiwan Chemical Substance Inventory (TCSI)

Toxic Substances Control Act (TSCA) Inventory

Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

USP Reference Standards are sold for chemical test and assay purposes only, and NOT for Disclaimer

human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard 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 Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. 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.

Material name: Zolmitriptan USP SDS US

1727009 Version #: 04 Revision date: 02-06-2020 Issue date: 08-31-2011

7/7

On inventory (vec/ne)*

Yes

No