U.S. Pharmacopeial Convention

SAFETY DATA SHEET

1. Identification

Product identifier Trihexyphenidyl Hydrochloride

Other means of identification

Catalog number1687006CAS number52-49-3

Synonyms Benzhexol hydrochloride

Chemical name 1-Piperidinepropanol, alpha-cyclohexyl-alpha-phenyl-, hydrochloride, (+-)-

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 name U. S. Pharmacopeia
Address 12601 Twinbrook Parkway

Rockville MD 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

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Warning

Hazard statement Harmful if swallowed.

Precautionary statement

Prevention Wash thoroughly after handling.

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

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 Potent pharmacologically active material.

3. Composition/information on ingredients

Substance

Material name: Trihexyphenidyl Hydrochloride

USP SDS US

% **Chemical name** Common name and synonyms **CAS** number Trihexyphenidyl Hydrochloride Benzhexol hydrochloride 52-49-3 100

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

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

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

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

Potent pharmacologically active material. Occupational exposure to small amounts may cause Most important

symptoms/effects, acute and physiological effects. Anticholinergic effects. delayed

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Perform gastric lavage and administer activated charcoal as a slurry. Do not induce vomiting. Maintain open airway and assist ventilation if needed. Tachydysrhythmias may respond to physostigmine or intravenous beta-blockers. Ventricular dysrhythmias may respond to intravenous sodium bicarbonate or lidocaine. For seizures, administer intravenous benzodiazepine. If seizures recur, consider phenobarbital. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte imbalances, and hypoxia. Intravenous benzodiazepine may be used to control agitation. Physostigmine may also be used control agitation and delirium. For severe hypertension, administer nitroprusside, labetalol, nitroglycerin, or phentolamine. Manage hyperthermia with external cooling. For rhabdomyolysis, administer saline. Monitor input and output, electrolytes, CK, and renal function. Administer diuretics if needed to maintain urine output. For hypotension, infuse isotonic fluid. If unresponsive, administer dopamine or norepinephrine. If hypotension is secondary to severe tachycardia, use esmolol to control tachycardia. Hemodialysis, hemoperfusion, peritoneal dialysis, and repeat-dose charcoal will not effectively remove anticholinergic agents.

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from **General information**

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. None known.

Unsuitable extinguishing

media

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

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 equipment/instructions

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

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.

1687006 Version #: 03 Revision date: 09-21-2018 Issue date: 09-14-2009

7. Handling and storage

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of Precautions for safe handling

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

No exposure limits noted for ingredient(s).

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

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 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. 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

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 state Solid. Powder. **Form**

Color White. Off-white. Odor Odorless. Slight. **Odor threshold** Not available. Ha Not available.

482 - 498.2 °F (250 - 259 °C) Melting point/freezing point

Initial boiling point and boiling

range

Not available.

Flash point Not available. Not available. **Evaporation rate** 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.

1687006 Version #: 03 Revision date: 09-21-2018 Issue date: 09-14-2009

USP SDS US

Explosive limit - upper (%) Not available.

< 0.0000001 kPa at 25 °C Vapor pressure

Vapor density Not available. Relative density Not available.

Solubility(ies)

Slightly soluble Solubility (water)

Solubility (other) Benzene: Very slightly soluble.

> Chloroform: Soluble. Ethanol: Soluble.

Ether: Very slightly soluble.

Methanol: Soluble.

Partition coefficient (n-octanol/water)

5.27

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

Other information

Chemical family Piperidine derivative (tertiary amine).

Molecular formula C20H31NO . HCI

337.93 Molecular weight

5.5 - 6 Solution: 1% pH in aqueous solution

10. Stability and reactivity

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

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 None known.

Hazardous decomposition

products

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

Anticholinergics: Flushing. Dry skin and mucous membranes. Dilated pupils. Change in vision.

11. Toxicological information

Information on likely routes of exposure

Inhalation Knowledge about health hazard is incomplete. Skin contact Knowledge about health hazard is incomplete. Knowledge about health hazard is incomplete. Eye contact

Harmful if swallowed. Based on information from therapeutic use, this material may cause: Ingestion

Anticholinergic effects.

Symptoms related to the

physical, chemical, and toxicological

Mood or mental change. Fever. Increased heart rate. Gastrointestinal disturbances. Urinary retention. Hypertension. Abnormal movement.

characteristics

Information on toxicological effects

Harmful if swallowed. Acute toxicity

Product Test Results Species

Trihexyphenidyl Hydrochloride (CAS 52-49-3)

Oral

LD50 Rat 1630 mg/kg

Skin corrosion/irritation Knowledge about health hazard is incomplete. Serious eye damage/eye

irritation

Knowledge about health hazard is incomplete.

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete.

Skin sensitization Knowledge about health hazard is incomplete. Knowledge about mutagenicity is incomplete. Germ cell mutagenicity Carcinogenicity Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Knowledge about health hazard is incomplete. Reproductive toxicity

> The National Collaborative Perinatal Project found no increase in major birth defects in the offspring of nine women treated with trihexyphenidyl during the first trimester of pregnancy.

Specific target organ toxicity -

single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity -

repeated exposure

Knowledge about health hazard is incomplete.

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

Further information Potent pharmacologically active material. Occupational exposure to small amounts may cause

physiological effects.

12. Ecological information

The product is not classified as environmentally hazardous. However, this does not exclude the **Ecotoxicity**

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.

No data available. Bioaccumulative potential Octanol/water partition coefficient log Kow

5 27

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.

The waste code should be assigned in discussion between the user, the producer and the waste Hazardous waste code

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

Not applicable.

the IBC Code

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

shipment.

1687006 Version #: 03 Revision date: 09-21-2018 Issue date: 09-14-2009

15. Regulatory information

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

Standard, 29 CFR 1910.1200.

Material name: Trihexyphenidyl Hydrochloride

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

Not regulated.

(SDWA)

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 | Inventory name | On inventory (yes/no)* |
|-----------------------------|--|------------------------|
| Australia | Australian Inventory of Chemical Substances (AICS) | Yes |
| Canada | Domestic Substances List (DSL) | Yes |
| 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) | Yes |
| 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

09-14-2009 Issue date 09-21-2018 **Revision date**

Version # 03

Material name: Trihexyphenidyl Hydrochloride

1687006 Version #: 03 Revision date: 09-21-2018 Issue date: 09-14-2009

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).

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