

SAFETY DATA SHEET

1. Identification

Product Identifier: Buprenorphine HCl Sublingual Tablets

Synonyms: 6,14-Ethenomorphinan-7-methanol, 17-(cyclopropylmethyl) alpha-(1,1-dimethylethyl)-4,5-epoxy-18,19-dihydro-3-hydroxy-6 methoxy-alpha-methyl-,hydrochloride, [5alpha, 7alpha (S)]-

National Drug Code (NDC): 50383-924-93
50383-930-93

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Not classifiable.
Health Hazards: Not determined.
Symbol(s): Not determined.
Signal Word: Not determined.

Hazard Statement(s): H302 Harmful if swallowed.
H332 Harmful if Inhaled.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H361 Suspect of damage fertility or the unborn child.
H362 May cause harm to breast-fed children.

Precautionary Statement(s): P201 Obtain special instruction before use.
P260 Do not breathe dust/fume/gas/mist/vapors/spray.
P263 Avoid contact during pregnancy/while nursing.

Hazards Not Otherwise Classified: Not classifiable
Supplementary Information: None.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Buprenorphine HCl	53152-21-9	6,14-Ethenomorphinan-7-methanol, 17-(cyclopropylmethyl)-alpha-(1,1-dimethylethyl)- 4,5-epoxy-18, 19-dihydro-3-hydroxy-6-methoxy-alpha-methyl-, hydrochloride, [5alpha, 7alpha (S)]-	C ₂₉ H ₄₁ NO ₄ •HCl	504.10	2% and 7.85%

This formula also contains Citric Acid, Corn Starch, Lactose Monohydrate, Mannitol, Povidone K30, Sodium Citrate Anhydrous and Sodium Stearyl Fumarate.

4. First Aid Measures

Ingestion:

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact:

Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact:

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation:

Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders:

Use personal protective equipment (see section 8).

Signs and Symptoms:

Consult the package insert for further information.

Medical Conditions Aggravated by Exposure:

Consult the package insert for further information.

SDS: Buprenorphine HCl Sublingual Tablets

Notes to Physician: If ingested, risks are similar to secondary effects and overdose of morphine-based products.

5. Firefighting Measures

Suitable Extinguishing Media: Use extinguishing media for type of surrounding fire. Sprayed water, CO₂, powder.

Unsuitable Extinguishing Media: High volume water jet.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: The product does not present any combustion danger.

Explosion Characteristics: The product does not present any combustion danger.

Other Specific Hazards: Not determined.

Special Protective Equipment/Precautions for Firefighters: Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Pick up in the most efficient manner and put in designated packaging.

Environmental Precautions: Do not pour into sewage system or natural environment.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store at a room temperature in airtight containers in a non humid and ventilated room. Store according to label and/or product insert information.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Buprenorphine HCl	Not established.

SDS: Buprenorphine HCl Sublingual Tablets

Engineering Controls:	Engineering controls should be used as the primary means to control exposures.
Respiratory Protection:	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).
Eyes Protection:	Safety glasses with side shields 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.
Hand Protection:	Wear 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 non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Skin Protection:	Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color:	Solid white color.
Odor:	Odorless.
Odor Threshold:	No data available.
pH:	No data available.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Soluble in alcohol and water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. Stability and Reactivity

Reactivity: No data available.

Chemical Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: No data available.

Conditions to Avoid (e.g., static discharge, shock, or vibration): Avoid impact, major temperatures and hygrometry changes.

Incompatible Materials: Strong acids and strong oxidants.

Hazardous Decomposition Products: CO, CO₂, HCl

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: Harmful if Inhaled. May cause allergy or asthma symptoms or breathing.

Ingestion: Harmful if Swallowed.

Skin Contact: No data available.

Eye Contact: No data available.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics: See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure: No data available.

Acute Toxicity:

Species	Route	Test Type	Dose
Rat	Oral	LD ₅₀	>2,000 mg/kg

Acute Toxicity – Dermal: No data available.

Acute Toxicity – Inhalation: No data available.

Corrosivity: No data available.

Dermal Irritation: No data available.

Eye Irritation: No data available.

Sensitization: No data available.

Toxicokinetics/Metabolism: No data available.

Target Organ Effects: No data available.

Reproductive Effects: No data available.

Carcinogenicity: No data available.

SDS: Buprenorphine HCl Sublingual Tablets

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

Mutagenicity: No data available.

Aspiration Hazard: No data available.

12. Ecological Information

Ecotoxicity

Aquatic: No data available.

Terrestrial: No data available.

Persistence and Degradability: No data available.

Bioaccumulative Potential: No data available.

Mobility in Soil: No data available.

Mobility in Environment: No data available.

Other Adverse Effects: No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number: Not applicable.

UN Proper Shipping Name: Not applicable.

Transport Hazard Class(es): Not applicable.

Packing Group: Not applicable.

Department of Transportation: Not regulated as a hazardous material.

International Air Transport Association (IATA): Not regulated as a dangerous good.

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA): Not listed.

CERCLA Hazardous Substance and Reportable Quantity: Not listed.

SARA 313: Not listed.

SARA 302: Not listed.

State Regulations

California Proposition 65: Not listed.

16. Other Information

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