



SDS: Buprenorphine and Naloxone Sublingual Tablets CIII

SAFETY DATA SHEET

1. Identification

Product Identifier:	Buprenorphine and Naloxone Sublingual Tablets CIII
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)]-; Naloxone Hydrochloride Dihydrate USP/EP (np) * Narcanti * Morphinan-6-one,4,5-epoxy-3,14-dihydroxy-17-(2-propenyl)-, hydrochloride, dihydrate, (5.alpha.)-
National Drug Code (NDC):	50383-294-93 50383-287-93
Recommended Use:	Buprenorphine and Naloxone Sublingual Tablets are indicated for the maintenance treatment of opioid dependence.
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 classifiable.
Symbol(s):	None.
Signal Word:	None.
Hazard Statement(s):	None.
Precautionary Statement(s):	None.
Hazards Not Otherwise Classified:	Not classifiable.
Supplementary Information:	While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
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)]-	53152-21-9	Buprenorphine Hydrochloride	C ₂₉ H ₄₁ NO ₄ •HCl	504.1	0.2% and 0.8%
Naloxone Hydrochloride Dihydrate USP/EP (np) * Narcanti * Morphinan-6-one, 4,5-epoxy-3,14-dihydroxy-17-(2-propenyl)-, hydrochloride, dihydrate, (5.alpha.)-	51481-60-8	Naloxone Hydrochloride	C ₁₉ H ₂₁ NO ₄ •ClH•2H ₂ O	399.87	0.05% and 0.2%

*The formula also contains Lactose Monohydrate, Mannitol Cornstarch, Povidone, Purified Water, Citric Acid Anhydrous, Sodium Citrate, Sodium Stearyl Fumarate, Acesulfame K Sweetener, Lemon Flavor and Lime Flavor.

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: The common side effects are headache, nausea, vomiting, increased sweating, drug withdrawal syndrome, constipation, decrease in sleep (insomnia), pain and swelling of the extremities.

Medical Conditions Aggravated by Exposure: No data available.

Notes to Physician: Prescription use of this product in the treatment of opioid dependence is limited to physicians who meet certain qualifying requirements, and who have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe this product for the treatment of opioid dependence and have been assigned a unique identification number that must be included on every prescription.

5. Firefighting Measures

Suitable Extinguishing Media: Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

Unsuitable Extinguishing Media: Do not use water jet as an extinguisher, as this will spread the fire.

Specific Hazards Arising from the Chemical

Hazardous Combustion Products: No data available.

Other Specific Hazards: Closed containers may explode from the heat of fire.

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

6. Accidental Release Measures

Personal Precautions: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

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Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

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 according to label and/or product insert information. Store away from oxidizers, acids, and bases.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Buprenorphine Hydrochloride	0.001 mg/m ³ TWA
Naloxone Hydrochloride	No data available.

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: 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:	Uncoated, round, white tablet.
Odor:	No data available.
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 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:	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability:	Material is stable under recommended storage conditions.
Possibility of Hazardous Reactions:	None known under conditions of normal use.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Contact with incompatible materials. Avoid dispersal of dust in the air.
Incompatible Materials:	Strong oxidizing agents.
Hazardous Decomposition Products:	None known.

11. Toxicological Information**Information on the Likely Routes of Exposure**

Inhalation:	May cause respiratory tract irritation.
Ingestion:	May cause irritation and malaise.
Skin Contact:	May cause irritation.
Eye Contact:	May cause eye irritation.

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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:

Compound	Species	Route	Test Type	Dose
Buprenorphine Hydrochloride	Rat	Oral	LD ₅₀	>1,000 mg/kg 600 mg/kg
Buprenorphine Hydrochloride	Mouse	Oral	LD ₅₀	800 mg/kg 261 mg/kg
Naloxone Hydrochloride	Rat	Oral	LD ₅₀	>1,000 mg/kg

Acute Toxicity – Dermal:

No data available.

Acute Toxicity – Inhalation:

No data available.

Corrosivity:

No data available.

Dermal Irritation:

Prolonged skin contact may cause temporary irritation.

Eye Irritation:

Dust may irritate the eyes.

Sensitization:

No data available.

Toxicokinetics/Metabolism:

No data available.

Target Organ Effects:

No data available.

Reproductive Effects:

Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. This product passes into breast milk. Breast-feeding is not advised in mothers being treated.

Carcinogenicity:

Animal experiments showed a statistically significant number of dose-related increases in Leydig cell tumors.

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:

Combination of Buprenorphine and Naloxone was not mutagenic in a bacterial mutation assay (Ames test) using four strains of *S. typhimurium* and two strains of *E. coli*.

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**

Chemical Name	UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable	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): This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.

CERCLA Hazardous Substance and Reportable Quantity: Not listed.

SARA 313: Not listed.
SARA 302: Not listed.

State Regulations

U.S. State Right-to-Know Regulations:

Chemical Name	Massachusetts	New Jersey	Pennsylvania
Buprenorphine Hydrochloride	Not listed	Not listed	Not listed
Naloxone Hydrochloride	Not listed	Listed	Listed

California Proposition 65: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. Other Information

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