



# Buprenorphine Hydrochloride Injection C-III

## Safety Data Sheet

According To Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules And Regulations And According To The Hazardous Products Regulation (December 15, 2022).

Revision Date:

Date of Issue: 04/08/2025

Version: 1.0

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Product Form:** Mixture

**Product Name:** Buprenorphine Hydrochloride Injection C-III

**Synonyms:** Buprenorphine hydrochloride

### 1.2 Recommended Use and Restrictions on Use

**Use Of The Substance/Mixture** : Indicated for management of pain severe enough to require an opioid analgesic and for which alternate treatments are inadequate.

**Restrictions On Use** : No additional information available

### 1.3. Name, Address, and Telephone of the Responsible Party

#### Corporate

Endo USA Inc

870 Parkdale Rd

Rochester, MI 48307 USA

T 1-800-828-9393 (Phone)

1-201-829-9222 (Fax)

Website: [www.endo.com](http://www.endo.com)

Email: [medical.information@endo.com](mailto:medical.information@endo.com)

### 1.4. Emergency Telephone Number

**Emergency Number** : VelocityEHS  
(800)255-3924 (North America)  
+1 (813)248-0585 (International)

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the Substance or Mixture

#### GHS-US/CA Classification

Not classified.

### 2.2. Label Elements

#### GHS-US/CA Labeling

No labeling applicable according to 29 CFR 1910.1200 and the Hazardous Products Regulations (HPR) SOR/2022-272.

### 2.3 Hazards associated with known or reasonably anticipated uses

This product is a pharmaceutical product designed for administration to a patient by a qualified medical professional. No other uses are anticipated. If this product is used in unforeseeable chemical processes and not used as intended or reasonable, the hazards listed in Section 2.3 cannot cover all chemistries. Therefore, a Process Hazard Analysis (PHA) or other hazard assessment for additional specific end uses should be performed to ensure that hazards are fully understood, and adequate safety measures are in place. See Section 10 for relevant reactivity and stability information.

### 2.4. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

### 2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substance

Not applicable

### 3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Water	AQUA	(CAS-No.) 7732-18-5	80 – 100	Not classified.
Glucose	Anhydrous dextrose / Cartose / Cerelose / Corn sugar / Dextrose / Dextrose, anhydrous / D-Glucose / .delta.-Glucose / Glucose liquid / D-Glucose, anhydrous / Glucose, anhydrous / Grape sugar / Sugar, grape / GLUCOSE / anhydrous dextrose	(CAS-No.) 50-99-7	3 – 7	Combustible Dust

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Buprenorphine hydrochloride	Buprenorphine hydrochloride / 6,14-Ethenomorphinan-7-methanol, 17-(cyclopropylmethyl)-.alpha.-(1,1-dimethylethyl)-4,5-epoxy-18,19-dihydro-3-hydroxy-6-methoxy-.alpha.-methyl-, hydrochloride, (.alpha.S,5.alpha.,7.alpha.)- / 6,14-Ethenomorphinan-7-methanol, 17-(cyclopropylmethyl)-.alpha.-(1,1-dimethylethyl)-4,5-epoxy-18,19-dihydro-3-hydroxy-6-methoxy-.alpha.-methyl-, hydrochloride (1:1) / 6,14-Ethenomorphinan-7-methanol, 17-(cyclopropylmethyl)-.alpha.-(1,1-dimethylethyl)-4,5-epoxy-18,19-dihydro-3-hydroxy-6-methoxy-.alpha.-methyl-, hydrochloride, [5.alpha.,7.alpha.(S)]- / buprenorphine hydrochloride	(CAS-No.) 53152-21-9	< 0.1	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation:dust,mist), H332 Eye Irrit. 2, H319 Repr. 2, H361 Lact., H362 STOT SE 3, H336 STOT RE 2, H373 Combustible Dust
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\* The actual concentration of ingredient(s) is withheld as a trade secret in accordance with the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2022-272. Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%). Full text of H-phrases: see section 16

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of First-aid Measures

**General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

**Inhalation:** When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

**Skin Contact:** Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.

**Eye Contact:** Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

**Ingestion:** Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

### 4.2. Most Important Symptoms and Effects Both Acute and Delayed

**General:** Accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area.

**Inhalation:** Prolonged exposure may cause irritation.

**Skin Contact:** Prolonged exposure may cause skin irritation.

**Eye Contact:** May cause slight irritation to eyes.

**Ingestion:** Ingestion may cause adverse effects.

**Chronic Symptoms:** None expected under normal conditions of use.

### 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand. Naloxone is the specific antidote for opioid poisonings. Naloxone should be administered as soon as possible after exposure, then immediate transport to medical care initiated. Naloxone may only provide temporary antagonistic effects in the presence of opioids with long half lives, so multiple doses or continual IV administration may be required.

## SECTION 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Solutions do not burn. Use extinguishing media appropriate for surrounding fire.

**Unsuitable Extinguishing Media:** None known.

### 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** Product is not flammable.

**Explosion Hazard:** Product is not explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

### 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire.

**Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Hazardous Combustion Products:** Carbon and nitrogen oxides, chlorine compounds.

**Other Information:** No additional information available.

### 5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

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### SECTION 6: ACCIDENTAL RELEASE MEASURES

#### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

##### 6.1.1. For Non-Emergency Personnel

**Protective Equipment:** Use appropriate personal protective equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

##### 6.1.2. For Emergency Personnel

**Protective Equipment:** Equip cleanup crew with proper protection.

**Emergency Procedures:** Ventilate area. Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

#### 6.2. Environmental Precautions

Prevent entry to sewers and public waters.

#### 6.3. Methods and Materials for Containment and Cleaning Up

**For Containment:** Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

**Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material, then place in suitable container. Contact competent authorities after a spill.

#### 6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

### SECTION 7: HANDLING AND STORAGE

#### 7.1. Precautions for Safe Handling

**Additional Hazards When Processed:** Accidental injection may cause pain and swelling at the injection site. Sharps should be handled appropriately to minimize risk of accidents. Material may be biologically contaminated with pathogenic organisms during use.

**Precautions for Safe Handling:** Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray. Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program. In hospital and workplace settings, contaminated sharps are to be handled in accordance with established protocols.

**Handling Temperature:** See Section 7.2, Storage, for suggested temperature range.

**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures.

#### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

**Storage Conditions:** Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

**Incompatible Materials:** Strong acids, strong bases, strong oxidizers.

**Storage Temperature:** 20 – 25 °C (68 – 77 °F). Excursions permitted to 15°C to 30°C (59°F – 86°F). DO NOT FREEZE!

**Storage Area:** Keep away from heat.

#### 7.3. Specific End Use(s)

Indicated for management of pain severe enough to require an opioid analgesic and for which alternate treatments are inadequate.

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

#### 8.2. Exposure Controls

**Appropriate Engineering Controls:** Suitable eye/body wash equipment should be available in the vicinity of any potential exposure.

Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

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**Personal Protective Equipment:** Gloves. Protective clothing. Protective goggles or glasses.



**Materials for Protective Clothing:** Chemically resistant materials and fabrics.

**Hand Protection:** Wear protective gloves.

**Eye and Face Protection:** Chemical goggles or safety glasses.

**Skin and Body Protection:** Wear suitable protective clothing.

**Respiratory Protection:** If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

**Thermal Hazard Protection:** Not applicable.

**Environmental Exposure Controls:** Avoid unnecessary release into the environment.

**Other Information:** When using, do not eat, drink or smoke.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Color	: Clear/colourless liquid
Odor	: None
Odor Threshold	: No data available
pH	: 4.5 – 4.9
Evaporation Rate	: No data available
Melting Point	: $\approx 0^{\circ}\text{C}$ [Estimate] ( $32^{\circ}\text{F}$ )
Freezing Point	: $\approx 0^{\circ}\text{C}$ [Estimate] ( $32^{\circ}\text{F}$ )
Boiling Point	: $\approx 100^{\circ}\text{C}$ [Estimate] ( $212^{\circ}\text{F}$ )
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Lower Flammable Limit	: No data available
Upper Flammable Limit	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at $20^{\circ}\text{C}$	: No data available
Relative Density	: 1.0035
Specific Gravity	: No data available
Solubility	: Water: Soluble
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity, Kinematic	: No data available
Particle characteristics	: No data available

## SECTION 10: STABILITY AND REACTIVITY

### 10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

### 10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

### 10.3. Possibility of Hazardous Reactions, Including those Associated with Foreseeable Emergencies:

Hazardous polymerization will not occur.

### 10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials.

### 10.5. Incompatible Materials:

Strong acids, strong bases, strong oxidizers.

### 10.6. Hazardous Decomposition Products:

Thermal decomposition may produce: Carbon and nitrogen oxides, chlorine compounds.

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### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1. Information on Toxicological Effects - Product

**Likely routes of exposure:** Dermal, Eye Contact, Inhalation, Oral.

**Acute Toxicity (Oral):** Not classified.

**Acute Toxicity (Dermal):** Not classified.

**Acute Toxicity (Inhalation):** Not classified.

**LD50 and LC50 Data:**

No additional information available

**Skin Corrosion/Irritation:** Not classified.

**pH:** 4.5 – 4.9

**Eye Damage/Irritation:** Not classified.

**pH:** 4.5 – 4.9

**Respiratory or Skin Sensitization:** Not classified.

**Germ Cell Mutagenicity:** Not classified.

**Carcinogenicity:** Not classified.

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified.

**Reproductive Toxicity:** Suspected of damaging the unborn child.

**Specific Target Organ Toxicity (Single Exposure):** Not classified.

**Aspiration Hazard:** Not classified.

**Symptoms/Injuries After Inhalation:** Prolonged exposure may cause irritation.

**Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause slight irritation to eyes.

**Symptoms/Injuries After Ingestion:** Ingestion may cause adverse effects.

**Chronic Symptoms:** None expected under normal conditions of use.

#### 11.2. Information on Toxicological Effects - Ingredient(s)

**LD50 and LC50 Data:**

<b>Water (7732-18-5)</b>	
<b>LD50 Oral Rat</b>	> 90 ml/kg (Source: FOOD_JOURN)
<b>Buprenorphine (53152-21-9)</b>	
<b>LD50 Oral Rat</b>	600 mg/kg
<b>ATE US/CA (oral)</b>	800.00 mg/kg body weight
<b>ATE US/CA (dust, mist)</b>	1.50 mg/l/4h
<b>Glucose (50-99-7)</b>	
<b>LD50 Oral Rat</b>	25800 mg/kg (Source: NLM_CIP)

### SECTION 12: ECOLOGICAL INFORMATION

#### 12.1. Toxicity

No additional information available

#### 12.2. Persistence and Degradability

<b>Buprenorphine Hydrochloride Injection C-III</b>	
<b>Persistence and Degradability</b>	Expected to be biodegradable.

#### 12.3. Bioaccumulative Potential

<b>Buprenorphine Hydrochloride Injection C-III</b>	
<b>Bioaccumulative Potential</b>	Not expected to bioaccumulate.

#### 12.4. Mobility in Soil

<b>Buprenorphine Hydrochloride Injection C-III</b>	
<b>Ecology - Soil</b>	Leaches into groundwater.

#### 12.5. Other Adverse Effects

**Other Adverse Effects:** None known.

**Other Information:** Avoid release to the environment.

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### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1. Waste treatment methods

**Waste Treatment Methods:** Incineration is the preferred method for disposal of waste product. Can be landfilled, when in compliance with local regulations.

**Sewage Disposal Recommendations:** Do not dispose of waste into sewer. Do not empty into drains.

**Waste Disposal Recommendations:** Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

**Additional Information:** Biologically contaminated materials should be incinerated. Product is a Drug Enforcement Agency (DEA) Controlled Substance (Schedule C-III); ensure that all regulations for the disposal of controlled products are followed.

**Ecology - Waste Materials:** Avoid release to the environment.

### SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

#### 14.1. In Accordance with DOT

Not regulated for transport

#### 14.2. In Accordance with IMDG

Not regulated for transport

#### 14.3. In Accordance with IATA

Not regulated for transport

#### 14.4. In Accordance with TDG

Not regulated for transport

### SECTION 15: REGULATORY INFORMATION

#### 15.1. US Federal Regulations

##### Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

##### Glucose (50-99-7)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

#### 15.2. US State Regulations

Neither this product nor its chemical components appear on any US state lists, or its chemical components are not required to be disclosed.

#### 15.3. Canadian Regulations

##### Water (7732-18-5)

Listed on the Canadian DSL (Domestic Substances List)

##### Glucose (50-99-7)

Listed on the Canadian DSL (Domestic Substances List)

### SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

**Date of Preparation or Latest** : 04/08/2025

**Revision**

**Other Information** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2022-272.

#### GHS Full Text Phrases:

Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Lact.	Reproductive toxicity, Additional category, Effects on or via lactation
Repr. 2	Reproductive toxicity, Category 2
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Narcosis

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H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H336	May cause drowsiness or dizziness.
H361s	Suspected of damaging fertility or the unborn child
H362	May cause harm to breast-fed children.
H373	May cause damage to organs through prolonged or repeated exposure.

### Glossary of Data Source Abbreviations

ATSDR: Agency for Toxic Substances and Disease Registry (U.S. Department of Health and Human Services)	FOOD_JOURN: Food Research Journal (1956)
AU_WES: Australia WES	IARC: The International Agency for Research on Cancer
CHEMVIEW: ChemView (U.S. Environmental Protection Agency)	IDLH: National Institute for Occupational Health and Safety Immediately Dangerous to Life or Health Value Profiles
EC_RAR: European Commission Renewal Assessment Report	IUCLID: International Uniform Chemical Information Database
EC_SCOEL: European Commission Scientific Committee on Occupational Exposure Limits	JAPAN_GHS: Japan GHS Basis for Classification Data
ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals Reports	JP_J-CHECK: Japan J-Check
ECHA_API: European Chemicals Agency API	KR_NIER: South Korea National Institute of Environmental Research Evaluations
ECHA_RAC: ECHA Committee for Risk Assessment	NICNAS: Australia National Industrial Chemicals Notification and Assessment Scheme
EFSA: European Food Safety Authority	NIOSH: National Institute for Occupational Health and Safety (U.S. Department of Health and Human Services)
EPA: U.S. Environmental Protection Agency	NLM_CIP: National Library of Medicine ChemID plus database
EPA_AEGL: Acute Exposure Guideline Levels (U.S. Environmental Protection Agency)	NLM_HSDB: National Library of Medicine Hazardous Substance Data Bank
EPA_FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act Reregistration Eligibility Decision (U.S. Environmental Protection Agency)	NLM_PUBMED: National Library of Medicine PubMed database
EPA_HPVS: High Production Volume Chemicals (U.S. Environmental Protection Agency)	NTP: National Toxicology Program
EPA_TRED: Risk Assessment for Tolerance Reassessment Eligibility Decision (U.S. Environmental Protection Agency)	NZ_CCID: New Zealand Chemical Classification and Information Database
EU_CLH: European Union Harmonised Classification and Labelling Proposal	OECD_EHSP: Environment, Health, and Safety Publication (Organisation for Economic Co-operation and Development)
EU_RAR: European Union Risk Assessment Report	OECD_SIDS: Screening Information Data Sets (Organisation for Economic Co-operation and Development)
	WHO: World Health Organization

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*

NA GHS SDS 2024 (Can, US)