

SAFETY DATA SHEET

Preparation Date: 5/18/2016

Revision Date: 5/18/2016

Revision Number: G1

1. IDENTIFICATION

Product identifier

Product code: B1637
Product Name: BUPRENORPHINE HYDROCHLORIDE (CIII), USP

Other means of identification

Synonyms: No information available
CAS #: 53152-21-9
RTECS # KM7758000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Drug. Medication.
Uses advised against No information available

Supplier: Spectrum Chemical Mfg. Corp
 14422 South San Pedro St.
 Gardena, CA 90248
 (310) 516-8000

Order Online At: <https://www.spectrumchemical.com>

Emergency telephone number Chemtrec 1-800-424-9300
Contact Person: Martin LaBenz (West Coast)
Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral	Category 4
Reproductive toxicity	Category 2

Label elements

Warning

Hazard statements

Harmful if swallowed

Suspected of damaging fertility or the unborn child



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Do not eat, drink or smoke when using this product

Wear protective gloves/protective clothing/eye protection/face protection

Wash face, hands and any exposed skin thoroughly after handling

Precautionary Statements - Response

Call a POISON CENTER or doctor/physician if you feel unwell

Rinse mouth.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Buprenorphine Hydrochloride 53152-21-9	53152-21-9	100

4. FIRST AID MEASURES

First aid measures

General Advice:

National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

Skin Contact:

Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.

Product code: B1637

Product name: BUPRENORPHINE
HYDROCHLORIDE (CIII), USP

2 / 11

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If eye irritation persists, consult a specialist.

Inhalation: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Obtain medical attention.

Ingestion: Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms May cause eye/skin irritation. May cause irritation of respiratory tract. May cause central nervous system effects. May cause depression. May cause drowsiness or dizziness. tiredness. Insomnia. Confusion. Hallucinations. May cause cardiovascular effects. Chest tightness or pain. Hypertension. Hypotension. Weak, rapid pulse or rapid heart rate (Tachycardia). Heart palpitations. May cause nausea, headache, vomiting. May cause constipation or diarrhea. Dyspnea (Shortness of breath and difficulty breathing). May cause cyanosis. May cause decreased urination. Difficult/painful and/or frequent urination. May affect the liver. May cause loss of appetite. May cause anorexia. Muscle weakness. May cause muscle and joint pain. Pinpoint pupils.

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically

Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste

5. FIRE-FIGHTING MEASURES

Extinguishing Media

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

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: Carbon oxides; nitrogen oxides; hydrogen chloride

Specific hazards: May be combustible at high temperatures

Special Protective Actions for Firefighters

Specific Methods: No information available.

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Use personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with skin, eyes and clothing. Avoid breathing dust. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. All equipment used when handling the product must be grounded. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not ingest. Do not breathe dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Protect from light. Sensitive to light. Store in light-resistant containers. Store away from incompatible materials.

Incompatible Materials:

Strong oxidizing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
Buprenorphine Hydrochloride 53152-21-9	None	None	None	None

Canada

Components	Alberta	British Columbia	Ontario	Quebec
Buprenorphine Hydrochloride 53152-21-9	None	None	None	None

Australia and Mexico

Components	Australia	Mexico
Buprenorphine Hydrochloride 53152-21-9	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection:	Goggles or Safety glasses with side-shields
Skin and body protection:	Long sleeved clothing. apron. Gloves.
Respiratory protection:	Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent. .
Hygiene measures:	Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	Appearance: Crystalline powder.	Color: White.
Odor: No information available	Taste No information available	Formula: C29-H41-N-O4.HCl
Molecular/Formula weight: 504.10	Flammability: No information available	Flashpoint (°C/°F): No information available.
Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	pH: No information available	Melting point/range(°C/°F): 265-271 °C/509-519.8 °F
Decomposition temperature(°C/°F): No information available	Boiling point/range(°C/°F): No information available	Bulk density: No information available
Density (g/cm3): No information available	Specific gravity: No information available	Vapor pressure @ 20°C (kPa): No information available
Evaporation rate: No information available	Vapor density: No information available	VOC content (g/L): No information available
Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water): No information available	Viscosity: No information available
Miscibility: No information available	Solubility: Sparingly soluble in water	

10. STABILITY AND REACTIVITY

Reactivity

May react with strong oxidizers

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Incompatible materials. Avoid dust formation.

Incompatible Materials: Strong oxidizing agents.

Hazardous decomposition products: Carbon oxides. Nitrogen oxides (NOx). Hydrogen chloride.

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:

Inhalation. Ingestion.

Acute Toxicity

Component Information

Buprenorphine Hydrochloride - 53152-21-9

LD50/oral/rat = > 1 g/kg Oral LD50 Rat

LD50/oral/mouse = 800 mg/kg

LD50/dermal/rabbit = No information available

LD50/dermal/rat = No information available

LC50/inhalation/rat = No information available

LC50/inhalation/mouse = No information available

Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =

VALUE- Acute Tox Oral = >1000mg/kg

LD50/oral/mouse =

Value - Acute Tox Oral = 800mg/kg

LD50/dermal/rabbit

VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat

VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat

VALUE-Vapor = No information available

VALUE-Gas = No information available

VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse

VALUE-Vapor = No information available

VALUE - Gas = No information available

VALUE - Dust/Mist = No information available

Symptoms**Skin Contact:** May cause skin irritation.**Eye Contact:** May cause eye irritation.**Inhalation** May cause respiratory tract irritation.

Ingestion Harmful if swallowed. May cause nausea. May cause vomiting. May cause constipation. May cause flatulence. May cause coughing. May cause diarrhea. May cause abdominal pain. May cause headache. May affect respiration (respiratory depression). May cause difficulty breathing. May cause cyanosis. May cause flushing and sweating. May cause painful or difficult urination. May affect eyes (pinpoint pupils). May cause weakness. May cause chest pain. May affect the cardiovascular system (hypotension). May affect the cardiovascular system (hypertension). May affect the cardiovascular system (palpitations). May affect the cardiovascular system (tachycardia). May affect nervous system (numbness, tingling). May affect behavior/central nervous system (dizziness, drowsiness). May affect behavior/central nervous system (convulsions, seizures). May affect behavior/central nervous system (analgesia). May affect behavior/central nervous system (somnolence). May affect behavior/central nervous system (excitement). May affect behavior/central nervous system (confusion). May affect behavior/central nervous system (tiredness). May cause fatigue. May cause muscle weakness. May cause joint and muscle pain.

Ingestion: May affect behavior/central nervous system (hallucinations, insomnia, slurred speech, feeling drunk, agitation, trouble concentrating, euphoria, depression, restlessness, loss of consciousness). May cause decreased urination

Aspiration hazard No information available**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

Chronic Toxicity It may be habit forming. Prolonged or repeated ingestion may affect the liver (Hepatitis, jaundice). Prolonged or repeated ingestion may cause loss of appetite. Prolonged and repeated ingestion may cause weight loss or anorexia. Prolonged or repeated ingestion may cause symptoms similar to that of acute ingestion.

Sensitization: No information available**Mutagenic Effects:** No information available**Carcinogenic effects:** Not considered carcinogenic

Components	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Buprenorphine Hydrochloride	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

Reproductive toxicity Suspected of damaging fertility or the unborn child

Reproductive Effects: No information available
Developmental Effects: There are no adequate and well-controlled studies in humans
Possible risk of harm to the unborn child

Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure No information available
STOT - repeated exposure No information available
Target Organs: No information available

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available

Mobility: No information available

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:
Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:
Empty containers should be taken for local recycling, recovery or waste disposal

Components	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Buprenorphine Hydrochloride	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: None
ERG No: No information available
Marine Pollutant: No data available
DOT RQ (lbs): No information available

14. TRANSPORT INFORMATION

Special Provisions No Information available
Symbol(s): No information available

TDG (Canada)

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant No Information available

ADR

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Packing Group: No information available
Subsidiary Risk: No information available

IMO / IMDG

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant No information available

RID

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

ICAO

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

IATA

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
ERG Code: No information available
Special Provisions No information available

15. REGULATORY INFORMATION

International Inventories

Components	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
<i>Buprenorphine Hydrochloride</i>	Not Listed	Not present	Not present	Not present	Not present	Present	Present 258-396-8

U.S. Regulations

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm (See table below)

Components	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Buprenorphine Hydrochloride	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
<i>Buprenorphine Hydrochloride</i>	None	None	None	None	None

U.S. TSCA

Components	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
<i>Buprenorphine Hydrochloride</i>	Not Applicable	Not Applicable

Canada

WHMIS hazard class:

Non-controlled

Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

Components	Canada (DSL)	Canada (NDSL)
Buprenorphine Hydrochloride	Not Listed	Not Listed

Components	CEPA Schedule I - Toxic Substances
Buprenorphine Hydrochloride	Not listed

Components	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Buprenorphine Hydrochloride	Not listed

EU Classification

R-phrases)

R22 - Harmful if swallowed.

R63 - Possible risk of harm to the unborn child.

Product code: B1637

Product name: BUPRENORPHINE
HYDROCHLORIDE (CIII), USP

10 / 11

S -phrase(s)

S46 - If swallowed, seek medical advice immediately and show this container or label.

S36/37 - Wear suitable protective clothing and gloves.

Components	Classification	Concentration Limits:	Safety Phrases
Buprenorphine Hydrochloride		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

Xn - Harmful.

Xn

**16. OTHER INFORMATION**

Preparation Date: 5/18/2016
Revision Date: 5/18/2016
Prepared by: Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet