

Safety Data Sheet



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Issued: 13 Jun 2022

1. Identification

Product Identifier	Hydrocodone Bitartrate
Other means of identification	
Internal item number	82393-0123
CAS number	34195-34-1
Synonyms	Dihydrocodeione bitartrate hydrate
Chemical name	Morphinan-6-one, 4,5-epoxy-3-methoxy-17-methyl-, (5 α)-, [R-(R*,R*)]-2,3-dihydroxybutanedioate (1:1), hydrate (2:5)
Relevant use and restrictions:	No further information available.
Application of substance:	Active pharmaceutical ingredient.
Manufacturer/Supplier information	
Company name	Pharma Source Direct
Address	8591 Prairie Trail Drive, Ste C-600 Englewood, CO 80112
Website	www.pharmasd.com
Emergency phone number	Infotrac: 1-800-535-5053

2. Hazard(s) Identification

Physical hazards	Not classified	
Health hazards	Acute toxicity, oral	Category 4
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
OSHA defined hazards	Not classified	
Label elements		

Signal word	Warning
Hazard statement	Harmful if swallowed. May cause drowsiness or dizziness.
Precautionary statement	
Prevention	Use only outdoors or in a well-ventilated area. Wash thoroughly after handling. Do not eat, drink or smoke when using this product.
Response	If swallowed: Call a poison center/doctor/medical professional/ if you feel unwell. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor/medical professional. Rinse mouth.
Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/ international regulations.

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Hazards not otherwise classified (HNOC)

Not classified.

3. Composition/Information on Ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Hydrocodone Bitartrate	Dihydrocodeione bitartrate hydrate	34195-34-1	100

4. First-aid Measures

Inhalation	Move to fresh air. Call a POISON CENTER or doctor/physician if you feel unwell.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
Most important symptoms/effects, acute and delayed	Narcotic effects.
Indication of immediate medical attention and special treatment needed	Treatment of opioid analgesic overdose should be symptomatic and supportive and may include the following: Do not induce vomiting. Administer activated charcoal as a slurry. Monitor vital signs, pulse oximetry, and cardiac function. Monitor for CNS and respiratory depression. For respiratory depression, administer oxygen and assist ventilation. Protect airway with orotracheal intubation. For coma and respiratory depression, reverse with naloxone. Administer intravenously, intramuscularly, intratracheally, intranasally, or subcutaneously. A continuous infusion might be needed for long-acting opioids. For seizures, treat with intravenous benzodiazepines. If seizures persist, administer propofol or barbiturates. For hypotension, treat with an infusion of isotonic fluid. If hypotension persists, administer dopamine or norepinephrine. Hemodialysis and hemoperfusion are not recommended. (Poisindex)
General Information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from 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 spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
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Unsuitable extinguishing media

None known.

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 equipment/instructions

As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods

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

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

7. Handling and Storage

Precautions for safe handling

As a general rule, avoid all contact and inhalation of 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. Use of a designated area is recommended for handling of potent materials.

Conditions for safe storage, including any incompatibilities

Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure Controls & Personal Protection

Exposure limit values

Industrial Use

Material	Type	Value
Hydrocodone Bitartrate (CAS 34195-34-1)	STEL	100 micrograms/m3
	TWA	33 micrograms/m3

Biological limit values

No biological exposure limits noted for the ingredient(s)

Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

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Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses with sideshields 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.

Skin protection

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 nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other

For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

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).

Thermal hazards

Not available.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and Chemical Properties

Appearance	Fine, white crystals or crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Odorless.
Odor threshold	Not available.
pH	3.2 - 3.8 (2% solution)
Melting point/freezing point	244.4 - 262.4 °F (118 - 128 °C) ; also reported as 194 - 198 °C
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.

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Vapor pressure	< 0.0000001 kPa (77 °F (25 °C))
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Soluble.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Morphinan derivative; phenanthrene derivative.
Molecular formula	C ₁₈ H ₂₁ NO ₃ . C ₄ H ₆ O ₆ . 2 1/2H ₂ O
Molecular weight	494.49
Solubility (other)	Slightly soluble in ethanol; insoluble in ether and in chloroform.

10. Stability and Reactivity

Reactivity	No reactivity hazards known
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	Oxidizing agents. Alkalies. Strong acids. Heavy metal salts.
Hazardous decomposition products	NO _x . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological Information

Information on likely routes of exposure

Inhalation	Harmful if swallowed.
Skin contact	Due to lack of data the classification is not possible.
Eye contact	Due to lack of data the classification is not possible.
Ingestion	Due to lack of data the classification is not possible.
Symptoms related to the physical, chemical, and toxicological characteristics	Opioid analgesics: Dizziness. Drowsiness. Weakness. Restlessness. Euphoria. Depression. Agitation. Confusion. Hallucinations. Slurred speech. Nausea. Vomiting. Constipation. Decreased or difficult urination. Sweating. Flushing. Itching. Rash. Drowsiness. Cold and clammy skin. Difficulty breathing. Loss of consciousness. Pinpoint pupils. Muscle rigidity. Convulsions. Seizures.
Delayed and immediate effects of exposure	Opioid analgesics: Mood or mental changes. Low blood pressure. Slow or irregular heart rate. Hypothermia. Coma. Heart attack. Death.
Chronic effects	Opioid analgesics: Tolerance. Dependence.

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Medical conditions aggravated by exposure

Opioid analgesics: Liver impairment. Kidney impairment. Hypothyroidism. Seizure disorders. Asthma. Respiratory disorders. Heart arrhythmia. Alcoholism. History of drug abuse or dependence. Gallbladder disorders. Inflammatory bowel disease. Urinary disorders. Low blood pressure. Gastrointestinal obstruction. Adrenal gland problems. Sickle cell disease. Addison's disease. Concurrent use of monoamine oxidase inhibitors (MAOIs).

Acute toxicity

Harmful if swallowed.

Product

Species

Test Results

Hydrocodone Bitartrate (CAS 34195-34-1)

Oral

LD50

Rat

375 mg/kg, (anhydrous)

Skin corrosion/irritation

Due to lack of data the classification is not possible.

Serious eye damage/eye irritation

Due to lack of data the classification is not possible.

Respiratory sensitization

Due to lack of data the classification is not possible.

Skin sensitization

Due to lack of data the classification is not possible.

Germ cell mutagenicity

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

Mutagenicity

Ames S. typhimurium microsomal activation test

Result: Negative.

Basc test in Drosophila germ cells

Result: Negative.

Micronucleus test in mouse bone marrow

Result: Negative.

Carcinogenicity

Due to lack of data the classification is not possible. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Reproductive toxicity

Based on available data, the classification criteria are not met. Use of opioids during pregnancy may cause physical dependence in the fetus leading to respiratory difficulties and withdrawal symptoms (dehydration, irritability, tremors, excessive crying, diarrhea) in the newborn.

Epidemiological studies have not shown an association between therapeutic use of this material during pregnancy and an increased incidence of birth defects.

Reproductivity studies in animals have yielded mixed results.

Specific target organ toxicity - single exposure

Narcotic effects.

Specific target organ toxicity - repeated exposure

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

Aspiration hazard

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

12. Ecological Information

Ecotoxicity

No ecotoxicity data noted for the ingredient(s).

Persistence and degradability

No data is available on the degradability of this product.

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Bioaccumulative potential	Not available.
Mobility in soil	Not available.
Other adverse effects	Not available.

13. Disposal Considerations

Disposal instructions	Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Not available.
Hazardous waste code	Not regulated.
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	Empty containers should be taken to an approved waste handling site for recycling or disposal. 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 the IBC Code	No information available.
General information	It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory Information

US federal regulations	CERCLA/SARA Hazardous Substances - Not applicable.
	One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
SARA 302 Extremely hazardous substance	No
SARA 311/312 Hazardous chemical	No

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Other federal regulations

Safe Drinking Water Act (SDWA)

Not regulated.

Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)

Schedule II - 9193

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material 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)	No
Canada	Domestic Substances List (DSL)	No
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)	No
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
Phillipines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Unites 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)

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).

16. Other Information

Disclaimer

The information in this SDS has been compiled from sources considered dependable, but has not been independently verified. The company cannot guarantee the accuracy of information herein, and the statements contained should not be considered an official expression. The company will not assume liability for any loss, damage, and/or expense resulting from the use and/or misuse of this product in regards to handling, storage, and/or disposal.

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