

MSDS Material Safety Data Sheet

From: Mallinckrodt Inc.
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24 Hour Emergency Telephone: 314-654-1600
CHEMTREC: 1-800-424-9300

National Response in Canada
CANUTEC: 613-996-6666

Outside U.S. and Canada
Chemtrec: 703-527-3887

NOTE: CHEMTREC, CANUTEC and National Response Center emergency numbers to be used only in the event of chemical emergencies involving a spill, leak, fire, exposure or accident involving chemicals.

HYDROCODONE BITARTRATE

1. Product Identification

Synonyms: Morphinan-6-one, 4,5-alpha-epoxy-3-methoxy-17-methyl-tartrate(1:1); Hydrocodone Bitartrate ARS-(FOR R&D USE ONLY)

CAS No: 143-71-5

Molecular Weight: 494.50

Chemical Formula: $C_{27}H_{45}NO_7 \cdot C_4H_7O_4 \cdot 2.5 H_2O$

Product Codes: 1226, 1582, 1594, 4994

2. Composition/Information on Ingredients

Ingredient	CAS No.	Percent	Hazardous
Hydrocodone bitartrate	143-71-5	100%	Yes

3. Hazards Identification

Emergency Overview

DANGER! MAY BE FATAL IF SWALLOWED. HARMFUL IF INHALED OR ABSORBED THROUGH SKIN. ALLERGEN. EXPOSURE MAY PRODUCE ALLERGIC RESPONSE. NARCOTIC.

Potential Health Effects

Inhalation:

Narcotic. Can irritate the nasal and respiratory surfaces; sneezing and breathing difficulties can result. Inhalation of appreciable amounts may cause lung edema and typical symptoms of narcosis. See Ingestion below.

Ingestion:

Narcotic, extremely toxic. Can cause nausea, dizziness and constipation. Large doses can lead to central nervous system depression, collapse, respiratory or cardiac arrest and death.

Skin Contact:

Mild irritant, possibly capable of producing narcotic effects if absorbed through breaks, inflamed areas, etc.

Eye Contact:

Mild irritant and narcotic if absorbed by this route.

Chronic Exposure:

Can lead to habituation or addiction.

Aggravation of Pre-existing Conditions:

Some individuals may become sensitized from exposure and develop skin rashes, coughs, stuffy nose, asthma, and other allergic complaints. Sensitivity may develop soon after immediate contact or after years of exposure.

4. First Aid Measures

Inhalation:

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

Ingestion:

Induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person.

Skin Contact:

Immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Call a physician, immediately. Wash clothing before reuse.

Eye Contact:

Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately.

5. Fire Fighting Measures

Fire:

As with most organic solids, fire is possible at elevated temperatures or by contact with an ignition source.

Explosion:

Not considered to be an explosion hazard.

Fire Extinguishing Media:

Water spray, dry chemical, alcohol foam, or carbon dioxide.

Special Information:

In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

6. Accidental Release Measures

Ventilate area of leak or spill. Remove all sources of ignition. Wear appropriate personal protective equipment as specified in Section 8. Isolate hazard area. Keep unnecessary and unprotected personnel from entering. All clean-up operations should be witnessed by more than one individual.

Spills: Carefully sweep up material into an appropriate container and save for reclamation or disposal. Use non-sparking tools and equipment. Do not flush to sewer! The amount of material collected should be assessed and documented.

7. Handling and Storage

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect from physical damage and direct sunlight. CONTROLLED SUBSTANCE. Location of storage area must comply with all Drug Enforcement Agency regulations. Containers of this material may be hazardous when empty since they retain product residues (dust, solids); observe all warnings and precautions listed for the product.

8. Exposure Controls/Personal Protection

Airborne Exposure Limits:

None established.

Ventilation System:

A system of local and/or general exhaust is recommended to keep employee exposures as low as possible.

Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, "Industrial Ventilation, A Manual of Recommended Practices", most recent edition, for details.

Personal Respirator (NIOSH Approved)

For conditions of use where exposure to dust or mist is apparent and engineering controls are not feasible, a particulate respirator (NIOSH type N95 or better filters) may be worn. If oil particles (e.g. lubricants, cutting fluids, glycerine, etc.) are present, use a NIOSH type R or P filter. For emergencies or instances where the exposure levels are not known, use a full-face positive-pressure, air-supplied respirator. **WARNING:** Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.

Skin Protection:

Wear protective gloves and clean body-covering clothing.

Eye Protection:

Use chemical safety goggles. Maintain eye wash fountain and quick-drench facilities in work area.

Other Control Measures:

Allergic responses in sensitive individuals will disappear if removed from exposure.

9. Physical and Chemical Properties

Appearance:

White to pale yellow crystals.

Odor:

Odorless.

Solubility:

6 g in 100 g of water.

Specific Gravity:

No information found.

pH:

No information found.

% Volatiles by volume @ 21°C (70°F):

No information found.

Boiling Point:

Not applicable.

Melting Point:

~ 147°C (~ 297°F)

Vapor Density (Air=1):

No information found.

Vapor Pressure (mm Hg):

No information found.

Evaporation Rate (BuAc=1):

No information found.

10. Stability and Reactivity

Stability:

Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products:

Carbon dioxide and carbon monoxide may form when heated to decomposition.

Hazardous Polymerization:

Will not occur.

Incompatibilities:

Alkaloid precipitants, strong acids and oxidizers, heavy metal salts.

Conditions to Avoid:

No information found.

11. Toxicological Information

Oral rat LD50: 375 mg/kg, investigated as a reproductive effector. ("Humans are probably much more sensitive." -- Gosselin, Smith, Hodge, "Clinical Toxicology of Commercial Products" 5th Edition, 1984, p. II-239.)

Cancer Lists

Ingredient

---NTP Carcinogen---

Known Anticipated IARC Category

Hydrocodone bitartrate (143-71-5)

No

No

None

12. Ecological Information

Environmental Fate:

No information found.

Environmental Toxicity:

No information found.

13. Disposal Considerations

Notify site Drug Enforcement Agency compliance officer and local DEA office for appropriate disposal procedures. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations.

Dispose of container and unused contents in accordance with federal, state and local requirements.

14. Transport Information

Not regulated.

15. Regulatory Information

Chemical Inventory Status

Ingredient	TSCA	EC	Japan	Australia	Korea	---Canada---		
						DSL	NDSL	Phil.
Hydrocodone bitartrate (143-71-5)	Exempt	Yes	No	No	No	Yes	No	No

Federal, State & International Regulations

Ingredient	---SARA 302---		-----SARA 313-----		CERCLA	-RCRA-	-TSCA-
	RQ	TPQ	List	Chemical Catg.			
Hydrocodone bitartrate (143-71-5)	No	No	No	No	No	No	8(d)

Chemical Weapons Convention: No TSCA 12(b): No CDTA: No

SARA 311/312: Acute: Yes Chronic: Yes Fire: No Pressure: No Reactivity: No (Mixture / Solid)

Australian Hazchem Code: None allocated. Australian Poison Schedule: S8

WHMIS: This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

16. Other Information

NFPA Ratings:

Health: 3 Flammability: 1 Reactivity: 0

Label Hazard Warning:

DANGER! MAY BE FATAL IF SWALLOWED. HARMFUL IF INHALED OR ABSORBED THROUGH SKIN. ALLERGEN. EXPOSURE MAY PRODUCE ALLERGIC RESPONSE. NARCOTIC.

Label Precautions:

Do not breathe dust.
Keep container closed.
Use only with adequate ventilation.
Wash thoroughly after handling.
Avoid contact with eyes, skin and clothing.

Label First Aid:

In all cases call a physician immediately. If swallowed, induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes.

Product Use:

Medication: Analgesic agent

Revision Information:

MSDS Section(s) changed since last revision of document include: 8, 15.

Disclaimer:

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