

Safety Data Sheet

Hydrocodone Bitartrate Hemipentahydrate

Version 1.1

Revision Date: 11/05/2022

SECTION 1. IDENTIFICATION

Product name : Hydrocodone Bitartrate Hemipentahydrate

Synonyms : No data available

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical substance

Restricted Uses : No data available

Manufacturer or supplier's details

Company : Univar Solutions Canada Ltd.
Address : 64 Arrow Road
 North York, ON, M9M 2L9
 Canada

Emergency telephone number:

Local Emergency Contact : During Office hours Monday-Friday, 8.00 am - 4.30 pm (Pacific Standard Time) : 1-866-686-4827

Additional Information: : Responsible Party: Product Compliance Department
 E-mail: SDSNA@univarsolutions.com
 SDS Requests: 1-855-429-2661
 Website: www.univarsolutions.com

SECTION 2. HAZARD IDENTIFICATION

Hazardous Classification of the substance or mixture

Acute toxicity (Oral) : Category 4

Acute toxicity (Inhalation) : Category 4

Respiratory sensitisation : Sub-category 1A

Skin sensitisation : Sub-category 1A

Label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H302 + H332 Harmful if swallowed or if inhaled.
 H317 May cause an allergic skin reaction.
 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements : **Prevention:**
 P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
 P264 Wash skin thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.

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P271 Use only outdoors or in a well-ventilated area.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.
P284 Wear respiratory protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
P302 + P352 IF ON SKIN: Wash with plenty of water.
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Substance

Hazardous components

CAS-No.	Chemical name	% by Weight	Synonyms
34195-34-1	Hydrocodone Bitartrate	80 - 100	(4R,4aR,7aR,12bS)-9-methoxy-3-methyl-1,2,4,4a,5,6,7a,13-octahydro-4,12-methanobenzo-furo[3,2-e]isoquinolin-7-one;(2R,3R)-2,3-dihydrox

Actual concentration or concentration range is withheld as a trade secret

SECTION 4. FIRST-AID MEASURES

General advice : Move out of dangerous area.
Show this safety data sheet to the doctor in attendance.
Do not leave the victim unattended.
If inhaled : Call a physician or poison control centre immediately.

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	If unconscious, place in recovery position and seek medical advice.
In case of skin contact	: If on skin, rinse well with water.
In case of eye contact	: Flush eyes with water as a precaution. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing. If eye irritation persists, consult a specialist.
If swallowed	: Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Take victim immediately to hospital.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	: High volume water jet
Hazardous combustion products	: No hazardous combustion products are known
Further information	: Standard procedure for chemical fires. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Special protective equipment for firefighters	: Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation.
Environmental precautions	: Prevent product from entering drains. Prevent further leakage or spillage if safe to do so. If the product contaminates rivers and lakes or drains inform respective authorities.
Methods and materials for containment and cleaning up	: Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	: Avoid dust formation. Provide appropriate exhaust ventilation at places where dust is formed.
Advice on safe handling	: Avoid formation of respirable particles. Do not breathe vapours/dust. Avoid exposure - obtain special instructions before use.

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	Avoid contact with skin and eyes. For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area. Provide sufficient air exchange and/or exhaust in work rooms. Dispose of rinse water in accordance with local and national regulations. Persons susceptible to skin sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.
Conditions for safe storage	: Keep container tightly closed in a dry and well-ventilated place. Electrical installations / working materials must comply with the technological safety standards.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection	: In the case of dust or aerosol formation use respirator with an approved filter. Dust safety masks are recommended when the dust concentration is more than 10 mg/m³.
Hand protection	
Remarks	: The suitability for a specific workplace should be discussed with the producers of the protective gloves.
Eye protection	: Eye wash bottle with pure water Tightly fitting safety goggles
Skin and body protection	: Dust impervious protective suit Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Hygiene measures	: Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: crystalline
Colour	: white, light yellow
Odour	: odorless
Odour Threshold	: No data available
pH	: No data available
Freezing Point (Melting point/range)	: 147 °C (297 °F)
Boiling Point	: No data available
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: No data available
Upper explosion limit	: No data available

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Lower explosion limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Density	: No data available
Solubility(ies)	
Water solubility	: 60 g/l @ 20 °C (68 °F)
Solubility in other solvents	: No data available
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Thermal decomposition	: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: Stable under recommended storage conditions.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: No decomposition if stored and applied as directed.
	Dust may form explosive mixture in air.
Conditions to avoid	: None known.
Incompatible materials	: Strong oxidizing agents

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity****Components:****34195-34-1:**

Acute oral toxicity : Assessment: The component/mixture is moderately toxic after single ingestion.

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation**Components:****34195-34-1:**

Remarks: No data available

Serious eye damage/eye irritation**Components:****34195-34-1:**

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Remarks: No data available

Respiratory or skin sensitisation

Components:

34195-34-1:

Result: The product is a skin sensitiser, sub-category 1A.

Result: The product is a respiratory sensitiser, sub-category 1A.

ACGIH

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

STOT - single exposure

Components:

34195-34-1:

Exposure routes: Inhalation

Target Organs: respiratory tract irritation

Assessment: The substance or mixture is classified as specific target organ toxicant, single exposure, category 3 with respiratory tract irritation.

Further information

Product:

Remarks: No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

Product:

Additional ecological information : No data available

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SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

- Waste from residues : Dispose of in accordance with all applicable local, state and federal regulations.
For assistance with your waste management needs - including disposal, recycling and waste stream reduction, contact Univar Solutions ChemCare: 1-800-637-7922
- Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

TDG (Transportation of Dangerous Goods): Not regulated as a dangerous good

IATA (International Air Transport Association): Not regulated as a dangerous good

IMDG-Code: Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

This product has been classified according to the hazard criteria of the Hazardous Products Regulations (HPR) and the SDS contains all of the information required by the HPR.

The components of this product are reported in the following inventories:

- DSL : All components of this product are on the Canadian DSL

SECTION 16. OTHER INFORMATION

The information accumulated is based on the data of which we are aware and is believed to be correct as of the date hereof. Since this information may be applied under conditions beyond our control and with which we may be unfamiliar and since data made become available subsequently to the date hereof, we do not assume any responsibility for the results of its use. Recipients are advised to confirm in advance of need that the information is current, applicable, and suitable to their circumstances. This SDS has been prepared by Univar Solutions EHS Product Compliance Department (1-855-429-2661) SDSNA@univarsolutions.com.

Revision Date : 11/05/2022

Material number:
16175086,

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Key or legend to abbreviations and acronyms used in the safety data sheet			
ACGIH	American Conference of Government Industrial Hygienists	LD50	Lethal Dose 50%
AICS	Australia, Inventory of Chemical Substances	LOAEL	Lowest Observed Adverse Effect Level
DSL	Canada, Domestic Substances List	NFPA	National Fire Protection Agency
NDSL	Canada, Non-Domestic Substances List	NIOSH	National Institute for Occupational Safety & Health
CNS	Central Nervous System	NTP	National Toxicology Program
CAS	Chemical Abstract Service	NZIoC	New Zealand Inventory of Chemicals
EC50	Effective Concentration	NOAEL	No Observable Adverse Effect Level
EC50	Effective Concentration 50%	NOEC	No Observed Effect Concentration
EGEST	EOSCA Generic Exposure Scenario Tool	OSHA	Occupational Safety & Health Administration
EOSCA	European Oilfield Specialty Chemicals Association	PEL	Permissible Exposure Limit
EINECS	European Inventory of Existing Chemical Substances	PICCS	Philippines Inventory of Commercial Chemical Substances
MAK	Germany Maximum Concentration Values	PRNT	Presumed Not Toxic
GHS	Globally Harmonized System	RCRA	Resource Conservation Recovery Act
>=	Greater Than or Equal To	STEL	Short-term Exposure Limit
IC50	Inhibition Concentration 50%	SARA	Superfund Amendments and Reauthorization Act.
IARC	International Agency for Research on Cancer	TLV	Threshold Limit Value
IECSC	Inventory of Existing Chemical Substances in China	TWA	Time Weighted Average
ENCS	Japan, Inventory of Existing and New Chemical Substances	TSCA	Toxic Substance Control Act
KECI	Korea, Existing Chemical Inventory	UVCB	Unknown or Variable Composition, Complex Reaction Products, and Biological Materials
<=	Less Than or Equal To	WHMIS	Workplace Hazardous Materials Information System
LC50			Lethal Concentration 50%