

HYDROCODONE HYDROGEN TARTRATE 2.5-HYDRATE CRS

Y0000646



Xn : Harmful



6.1 : Toxic substances.

1 IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Trade name : HYDROCODONE HYDROGEN TARTRATE 2.5-HYDRATE CRS
Use : For laboratory tests and assays only, as described in the European Pharmacopoeia.
Directions for use : For any questions: www.edqm.eu/hd (HelpDesk)
Company identification : EDQM
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2 HAZARDS IDENTIFICATION

Risk Phrases : Harmful by inhalation and if swallowed. - May cause sensitization by inhalation and skin contact.
Adverse human health effects : Nervous system disorders. Exposure may produce an allergic reaction. Headache. Dry throat. Sweating. Dizziness. Sleepiness. Gastrointestinal disorders.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Components : This product is hazardous.

Substance name	Contents	CAS No	EC No	Annex No	Classification
Hydrocodone hydrogen tartrate 2.5-hydrate		34195-34-1	205-608-1	----	Xn: R20/22 R42/43

4 FIRST AID MEASURES

First aid measures

- **Inhalation** : Assure fresh air breathing. Rest. If you feel unwell, seek medical advice.
- **Skin contact** : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- **Eye contact** : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking, tears or redness persist.
- **Ingestion** : Rinse mouth. If swallowed, seek medical advice immediately and show this container or label.

In case of reactions described in hazards identification or other severe, immediate or persisting symptoms seek medical advice and call the nearest poison centre. Show the label and this safety data sheet.

5 FIRE-FIGHTING MEASURES

Extinguishing media

- **Suitable extinguishing media** : Water spray. Carbon dioxide. Dry powder.

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**HYDROCODONE HYDROGEN TARTRATE 2.5-
HYDRATE CRS****Y0000646****5 FIRE-FIGHTING MEASURES (continued)**

- Unsuitable extinguishing media : Do not use a heavy water stream.
- Surrounding fires : Use water spray or fog for cooling exposed containers.
- Protection against fire : Do not enter fire area without proper protective equipment, including respiratory protection.
- Hazardous combustion products : Incomplete combustion will generate poisonous carbon monoxide, carbon dioxide and other toxic gases.

6 ACCIDENTAL RELEASE MEASURES

- General precautions : Remove ignition sources. Evacuate area.
- Personal precautions : Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.
- Clean up methods : To clean the floor and all objects contaminated by this material, use : Water. . Avoid dust production. Ensure adequate ventilation.

7 HANDLING AND STORAGE

- Personal protection : Avoid all unnecessary exposure. Ensure prompt removal from eyes, skin and clothing.
- Technical protective measures : Material should be handled in a laboratory hood whenever possible.
- Handling : Handle in accordance with good industrial hygiene and safety procedures.
- Storage : HYDROCODONE HYDROGEN TARTRATE 2.5-HYDRATE CRS is not intended for long-term storage. Keep container tightly closed in a cool, well ventilated place.
- Storage - away from : All heat sources, including direct sunlight. Open flame. Sources of ignition. Sparks. Incompatible materials, see §10

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal protection



- * - Respiratory protection : Wear approved mask. (P3)
In case of insufficient ventilation, wear suitable respiratory equipment.
- Hand protection : Wear suitable gloves resistant to chemical penetration.
- Skin protection : Wear suitable protective clothing.
- Eye protection : Chemical goggles or safety glasses.
- Industrial hygiene : Provide local exhaust or general room ventilation.

9 PHYSICAL AND CHEMICAL PROPERTIES

- Chemical formula : C₂₂H₂₇NO₉, 2.5H₂O
- Molecular weight : 494.5
- Physical state at 20 °C : Powder.
- Colour : White.
- pH value : 3.2 - 3.8 (2%)
- Melting point [°C] : 194-198
- Boiling point [°C] : No data available.

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**HYDROCODONE HYDROGEN TARTRATE 2.5-
HYDRATE CRS****Y0000646****9 PHYSICAL AND CHEMICAL PROPERTIES (continued)**

Solubility in water : Complete.
Solubility : No data available.
Flash point [°C] : No data available.
Log P octanol / water at 20°C : No data available.

10 STABILITY AND REACTIVITY

Stability and reactivity : Stable under normal conditions.
Materials to avoid : Strong oxidizers.
Conditions to avoid : Moisture. Light. Heat.
Hazardous decomposition products : Carbon monoxide. Carbon dioxide.
Nitrogen oxides.
When heated to decomposition, emits dangerous fumes.
Hazardous reactions : None under normal conditions.
Hazardous polymerization : Will not occur.

11 TOXICOLOGICAL INFORMATION

RTECS nr : QD2840000 (anhydrous) (See actual entry in RTECS for complete information.)
Rat oral LD50 [mg/kg] : 250-375
Rabbit dermal LD50 [mg/kg] : No data available.
Rat inhalation LC50 [mg/L/4h] : No data available.
Acute toxicity : Nervous system disorders.
This material or its emissions may induce an allergic or sensitization reaction and
thereby aggravate existing systemic disease. Dizziness. Sleepiness.
Gastrointestinal disorders.
Chronic toxicity : No data available.
Sensitization : May cause sensitization by inhalation and skin contact.

12 ECOLOGICAL INFORMATION

Ecological effects information
LC50-96 Hour - fish [mg/L] : No data available.
EC50-48 Hour-Daphnia magna [mg/L] : No data available.
IC50-72h-Algae [mg/L] : No data available.
Biodegradation [%] : No data available.
Persistence - degradability : No data available.
Log P octanol / water at 20°C : No data available.
Bioaccumulative potential : No data available.

13 DISPOSAL CONSIDERATIONS

General : Dispose of this material and its container at hazardous or special waste collection
point.
Dispose in a safe manner in accordance with local/national regulations.

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14 TRANSPORT INFORMATION

Land transport

- Proper shipping name : ALKALOIDS, SOLID, N.O.S. / ALKALOID SALTS, SOLID, N.O.S. (Hydrocodone hydrogen tartrate 2.5-hydrate)
- UN No. : 1544
- ADR Class : 6.1
- ADR Packing group : III
- Labelling ADR



Air transport

- Proper shipping name : ALKALOIDS, SOLID, N.O.S. / ALKALOID SALTS, SOLID, N.O.S. (Hydrocodone hydrogen tartrate 2.5-hydrate)
- UN No. : 1544
- IATA - Class or division : 6.1
- IATA Packing group : III
- IATA-Label



15 REGULATORY INFORMATION

- Symbol(s)** : Xn : Harmful
- R Phrase(s)** : R20/22 : Harmful by inhalation and if swallowed.
R42/43 : May cause sensitization by inhalation and skin contact.
- S Phrase(s)** : S22 : Do not breathe dust.
S36/37/39 : Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately (show the label when possible).

16 OTHER INFORMATION

- Further information** : Revision - See : *
- List of relevant R phrases** : R20/22 : Harmful by inhalation and if swallowed.
R42/43 : May cause sensitization by inhalation and skin contact.

The contents and format of this SDS are in accordance with REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, as amended.

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