Safety Data Sheet
Dilaudid® (Hydromorphone Hydrochloride) Oral Solution C-II

Revision Date:
11 September, 2026

Section 1. Identification

Product Identifier

Product Identity Dilaudid® (Hydromorphone Hydrochloride) Oral Solution C-II

Other means of identification Dilaudid® 1 mg/mL Oral Solution

Relevant identified uses of the substance or mixture and uses advised against

Opioid analgesic.
Do not use without a prescription.

Details of the supplier of the safety data sheet

Company Name

Rhodes Pharmaceuticals LLC
4701 International Blvd W, Suite 307
Wilson, NC 27893

Emergency

24 hour Emergency Telephone No. Chemtrec (800) 424-9300; For all international transportation emergencies, call Chemtrec collect at (703) 527-3887

Customer Service: Phone: (252) 265 1755
Fax: (252) 265 1777

Section 2. Hazard(s) identification

Classification of the substance or mixture under OSHA's Hazard Communication Standard (1910.1200) revised 2024 (GHS revision 7).

Reproductive toxicity, category 2;H361D — Suspected of damaging the unborn child.

Label elements



Warning

H361d Suspected of damaging the unborn child.

Prevention

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves, eye protection, and face protection.

Response

P308+313 IF exposed or concerned: Get medical advice or attention.

Storage

P405 Store locked up.

Disposal

P501 Dispose of contents or container in accordance with local and national regulations.

Other hazards

This product contains no PBT/vPvB/vPvM chemicals.

This product contains no endocrine disrupting chemicals.

Does NOT contain component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS) per the US EPA PFASMASTER combined list of PFAS chemicals.

Section 3. Composition/information on ingredients

This product contains the following substances that present a hazard within the meaning of the OSHA's Hazard Communication Standard (1910.1200) revised 2024 (GHS revision 7).

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
Glycerin **CAS Number: 56-81-5** **Synonyms: Glycerol**	**7 - 13**	**Not Classified**	**No data available**
Hydromorphone hydrochloride **CAS Number: 71-68-1** **Synonyms: No available information**	**0.5 - 1.5**	**Acute toxicity(oral), category 3;H301** **Reproductive toxicity, category 2;H361D**	**No data available**

The actual concentration or concentration range is withheld as a trade secret.
*PBT/vPvB - PBT, vPvM or vPvB-substance.
The full texts of the phrases are shown in Section 16.

Section 4. First aid measures

Description of first aid measures

General In all cases of doubt, or when symptoms persist, seek medical attention. Never give anything by mouth to an unconscious person.

Inhalation Remove to fresh air, keep patient warm and at rest. If breathing is irregular or stopped, give artificial respiration. If unconscious, place in the recovery position and obtain immediate medical attention. Give nothing by mouth.

Eyes Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.

Skin Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.

Ingestion If swallowed obtain immediate medical attention. Keep at rest. Do NOT induce vomiting.

Most important symptoms and effects, both acute and delayed

Overview No specific symptom data available.
No chronic toxicity or long term toxicity information available. Treat symptomatically. See section 2 for further details.

Section 5. Fire-fighting measures

Extinguishing media

Use extinguishing measures appropriate to local circumstances and the surrounding environment.

Special hazards arising from the substance or mixture

Hazardous decomposition: No hazardous decomposition data available.

Advice for fire-fighters

As with all fires, wear positive pressure, self-contained breathing apparatus, (SCBA) with a full face piece and protective clothing. Persons without respiratory protection should leave area. Wear SCBA during clean-up immediately after fire. No smoking.

ERG Guide No. ---

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Put on appropriate personal protective equipment (see section 8).

Use good personal hygiene practices. Wash hands before eating, drinking, smoking, or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

Environmental precautions

Do not allow spills to enter drains or waterways.

Methods and material for containment and cleaning up

Prevent further leakage or spillage if safe to do so. Pick up and transfer to properly labeled containers.

Section 7. Handling and storage

Precautions for safe handling

Handle containers carefully to prevent damage and spillage.

Avoid contact with skin, eyes or clothing. Wash thoroughly after handling. Wash contaminated clothing before reuse.

See section 2 for further details. - [Prevention]

Conditions for safe storage, including any incompatibilities

Schedule II controlled substance; requires DEA-compliant storage. Keep containers tightly closed. Protect from light. Store at 25°C (77°F), excursions 15–30°C (59–86°F). Incompatible with strong oxidizers, acids, and bases.

Incompatible materials: Strong oxidizers, acids, bases.

See section 2 for further details. - [Storage]

Specific end use(s)
No data available.

Section 8. Exposure controls / personal protection

Control parameters

Exposure Limits

CAS No.	Ingredient	Source	Value
56-81-5	Glycerin	OSHA	5 mg/m^3 (Respirable fraction), 15 mg/m^3 (total dust)
		ACGIH	TWA: 3 mg/m^3 (respirable) 10 mg/m^3 (mist)
		NIOSH	No established RELs
71-68-1	Hydromorphone hydrochloride	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit

The exposure limits for oil mist are 5 mg/m^3 OSHA PEL and 5 mg/m^3 ACGIH.

Exposure controls

Respiratory Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. In the United States of America, if respirators are used, they are to be NIOSH-approved and part of a respiratory protection program instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific.

Eyes No special protective measures are necessary.

Skin No special protective measures are necessary.

Engineering Controls None under normal use conditions.

Other Work Practices Use good personal hygiene practices. Wash hands before eating, drinking, smoking, or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

See section 2 for further details.

Section 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical State	Liquid
Color	Clear, Colorless
Odor	Characteristic sweet odor
Odor threshold	Not Available

Melting point / freezing point	Not Available
Initial boiling point and boiling range	Not Available
Flammability (solid, gas)	Not Applicable
Upper/lower flammability or explosive limits	Lower Explosive Limit: Not Available Upper Explosive Limit: Not Available
Flash Point	Not Available
Auto-ignition temperature	Not Available
Decomposition temperature	Not Available
pH	Not Available
Kinematic viscosity	Not Available
Solubility in Water	Not Available
Partition coefficient n-octanol/water (Log Kow)	Not Available
Vapor pressure (Pa)	Not Available
Relative Density	Not Available
Vapor Density	Not Available
Evaporation rate (Ether = 1)	Not Available
VOC Content	Not Available

Other information

No other relevant information.

Section 10. Stability and reactivity

Reactivity

Hazardous Polymerization will not occur.

Chemical stability

Stable under normal circumstances.

Possibility of hazardous reactions

No data available.

Conditions to avoid

No data available.

Incompatible materials

Strong oxidizers, acids, bases.

Hazardous decomposition products

No hazardous decomposition data available.

Section 11. Toxicological information

Acute toxicity

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LC50, mg/L/4hr	Inhalation Dust/Mist LC50, mg/L/4hr	Inhalation Gas LC50, ppm
Glycerin - (56-81-5)	27,200.00, Rat - Category: NA	45,000.00, Guinea Pig - Category: NA	No data available.	No data available.	No data available.
Hydromorphone hydrochloride - (71-68-1)	199.00, Rat - Category: 3	No data available.	No data available.	No data available.	No data available.

Carcinogen Data

CAS No.	Ingredient	Source	Value
56-81-5	Glycerin	OSHA	Regulated Carcinogen: No;
		NTP	Known: No; Suspected: No;
		IARC	No
		ACGIH	No Established Limit
71-68-1	Hydromorphone hydrochloride	OSHA	Regulated Carcinogen: No;
		NTP	Known: No; Suspected: No;
		IARC	No
		ACGIH	No Established Limit

Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	---	Not Applicable
Serious eye damage/irritation	---	Not Applicable
Respiratory sensitization	---	Not Applicable
Skin sensitization	---	Not Applicable
Germ cell mutagenicity	---	Not Applicable
Carcinogenicity	---	Not Applicable
Reproductive toxicity	2	Suspected of damaging the unborn child.
STOT-single exposure	---	Not Applicable
STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable

Possible routes of entry:
Inhalation, ingestion, skin contact, and skin absorption.

Symptoms and effects, both acute and delayed:
No specific symptom data available.
No chronic toxicity or long term toxicity information available. Treat symptomatically.

Section 12. Ecological information

Toxicity
No additional information provided for this product. See Section 3 for chemical specific data.

Aquatic Ecotoxicity

Ingredient	96 hr LC50 fish, mg/L	48 hr EC50 crustacea, mg/L	ErC50 algae, mg/L
Glycerin - (56-81-5)	54,000.00, Oncorhynchus mykiss	1,955.00, Daphnia magna	No data available.
Hydromorphone hydrochloride - (71-68-1)	No data available.	No data available.	No data available.

Persistence and degradability
There is no data available on the preparation itself.

Bioaccumulative potential
Not Available

Mobility in soil
No data available.

Results of PBT and vPvB assessment
This product contains no PBT/vPvB/vPvM chemicals.

Other adverse effects
No data available.

Section 13. Disposal considerations

Waste treatment methods
Waste should not be released to sewers. Observe all federal, state, and local regulations when disposing of this substance.

Section 14. Transport information

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
UN number	Not Regulated	Not Regulated	Not Regulated
UN proper shipping name	Not Regulated	Not Regulated	Not Regulated
Transport hazard class(es)	Class: Not Applicable Sub Class: Not Applicable	Class: Not Applicable Sub Class: Not Applicable	Class: Not Applicable Sub Class: Not Applicable
Packing group	Not Applicable	Not Applicable	Not Applicable

Environmental hazards

IMDG Marine Pollutant: No;

Special precautions for user

Not Applicable

Section 15. Regulatory information

Regulatory Overview The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.

Classification of the substance or mixture under OSHA's Hazard Communication Standard (1910.1200) revised 2024 (GHS revision 7).

Toxic Substance Control Act (TSCA)

CAS Number	Ingredient	Toxic Substance Control Act (TSCA)	Comments	Status
0000056-81-5	Glycerin	Yes		ACTIVE
0000071-68-1	Hydromorphone hydrochloride	No		

EPCRA 302 Extremely Hazardous:
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 313 Toxic Chemicals:
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Carcinogens (>0.0%):
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Developmental Toxins (>0.0%):
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Female Repro Toxins (>0.0%):
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Male Repro Toxins (>0.0%):
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 Label Warning:

This product contains no chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

Section 16. Other information

Revision Date 11 September, 2026

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:

H301 Toxic if swallowed.

H361 Suspected of damaging fertility or the unborn child.

Disclaimer: The information presented herein is supplied as a guide to those who handle or use this product. Safe work practices must be employed when working with any materials. It is important that the end user makes a determination regarding the adequacy of the safety procedures employed during the use of this product.

Reviewed & Approved by: IES Engineers
Authored by: Quantum SDS

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