

Safety Data Sheet

Issuing date: 22Feb2018

Revision date: 15JUL2019

Revision number: 01

1. Identification of the substance/preparation and the company/undertaking

Product Identifier	Oxycodone Hydrochloride Oral Solution USP
Other means of identification	
NDC Number(s)	0121-4827-05; 0121-4827-10; 0121-0827-04; 0121-0827-16; 0121-4827-40
Synonyms	None
Recommended Use/Restrictions	
Recommended Use	Oxycodone Hydrochloride Oral Solution is an opioid agonist indicated for the management of moderate to severe pain where the use of an opioid analgesic is appropriate.
Uses advised against	Do not use except as recommended.
Supplier Information	
Company name	Pharmaceutical Associates, Inc.
Address	201 Delaware Street Greenville, SC 29605
Telephone	864 - 277 - 7282
Emergency telephone number	CHEMTREC: 800 - 424 - 9300

2. Hazards Identification

Classification	Not classified
Physical hazards	Not classified
Chemical Family	None
Label elements	
Hazard symbol	None
Signal word	Warning
Hazard statement	This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.
Additional hazard Information	
Short term	Most common adverse reactions are nausea, constipation, vomiting, headache, itching, trouble sleeping, dizziness, weakness, drowsiness, sweating, lightheadedness.
Long term	No data available.

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Known Clinical Effects

Acute overdose with Oxycodone Hydrochloride Oral Solution can be manifested by respiratory depression (a decrease in respiratory rate and/or end tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, bradycardia, hypotension, pulmonary edema, cardiac arrest, and death.

Oxycodone Hydrochloride Oral Solution may cause miosis, even in total darkness. Pinpoint pupils are a sign of opioid overdose but are not pathognomonic (e.g., pontine lesions of hemorrhagic or ischemic origin may produce similar findings). Marked mydriasis rather than miosis may be seen with hypoxia in overdose situations

EU Indication of danger

Not classified.

Emergency overview

Seek medical attention in case of accidental exposure or overdose. The product is generally safe when used as prescribed.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential of exposure in your workplace.

Precautionary statements

Prevention

Observe good industrial hygiene practices.

Skin Contact

Wash hands after handling

Storage

All opioids, including Oxycodone Hydrochloride Oral Solution USP, are liable to diversion and misuse both by the general public and healthcare workers and should be handled accordingly.

Dispense in a tight, light-resistant container as defined in the USP/NF.

Keep in secured area and protect from diversion.

Store at 20° to 25°C (68° to 77°F)

Disposal

Incineration of waste at an approved USEPA incinerator is recommended.

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3. Composition/Information on ingredients

Substances

Chemical name	CAS-No	mg/5 mL	Trade Secret
Oxycodone Hydrochloride	124-90-3	5 mg	
Sorbitol	Mixture		X
Citric Acid Anhydrous	77-92-9		X
Sodium Citrate Dihydrate	6132-04-3		X
Sodium Benzoate	532-32-1		X
Saccharin Sodium	6155-57-3		X
FD&C Red #40	25956-17-6		X
Artificial Raspberry Flavor	Mixture		X

4. First aid measures

Eye contact

Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic / supportive care as necessary

Skin contact

Wash off with soap and water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic / supportive care as necessary

Inhalation

If signs of toxicity occur seek medical attention. Provide symptomatic / supportive care as necessary.

Ingestion

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic / supportive care as necessary.

Give primary attention to the re-establishment of a patent airway and institution of assisted or controlled ventilation. Supportive measures (including oxygen and vasopressors) should be employed in the management of circulatory shock and pulmonary edema accompanying overdose as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation.

The pure opioid antagonists, naloxone or nalmefene, are specific antidotes to respiratory depression resulting from opioid overdose. Since the duration of reversal is expected to be less than the duration of action of oxycodone hydrochloride, carefully monitor the patient until spontaneous respiration is reliably re-established. If the response to opioid antagonists is suboptimal or only brief in nature, administer additional antagonist as directed by the manufacturer of the product.

Do not administer opioid antagonists in the absence of clinically significant respiratory or circulatory depression secondary to oxycodone overdose.

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Administer such agents cautiously to persons who are known, or suspected to be physically dependent on oxycodone. In such cases, an abrupt or complete reversal of opioid effects may precipitate an acute abstinence syndrome.

In an individual physically dependent on opioids, administration of the usual dose of the antagonist will precipitate an acute withdrawal syndrome. The severity of the withdrawal symptoms experienced will depend on the degree of physical dependence and the dose of the antagonist administered. Reserve use of an opioid antagonist for cases where such treatment is clearly needed. If it is necessary to treat serious respiratory depression in the physically dependent patient, initiate administration of the antagonist with care and titrate with smaller than usual doses.

Most important symptoms/effects, acute and delayed

Oxycodone can cause serious side effects, including death. Respiratory depression is the chief hazard. Other serious side effect include: slowed breathing, shallow breathing, feeling faint, dizzy confused, or any other unusual symptoms.

Indication of immediate medical attention and special treatment needed, if necessary

Immediate medical attention is required if overdose is suspected. In the case of overdose, the primary management should be the reestablishment of adequate ventilation with mechanical assistance of respiration, if required. Supportive measures (including oxygen and vasopressors) should be employed in the management of circulatory shock and pulmonary edema accompanying overdose as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation. Treat symptomatically.

Indication of immediate medical attention and special treatment needed, if necessary

Immediate medical attention is required if overdose is suspected.

Notes to Physician

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

Specific hazards arising from the chemical

During fire, gases hazardous to health may be formed.

Explosion data

No unusual fire or explosion data notes.

Protective equipment and precautions for firefighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus

6. Accidental release measures

Personal precautions, protective equipment, and emergency procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (See Section 8). Minimize exposure.

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Environmental precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and materials for containment and cleaning up

Wipe up with absorbent material. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended. Controlled substances must be destroyed following DEA guidelines for witnessed destruction of the product beyond reclamation.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground

7. Handling and storage

Precautions for safe handling

Handling

No special handling required for hazard control under conditions of normal product use. In the US, oxycodone hydrochloride is a Schedule II controlled substance. Additional training may be required for handling this material.

Conditions for safe storage, including any incompatibilities

Storage

No special storage required for hazard control. For product protection, follow storage recommendations on the case label, primary product label or the product insert.

Incompatible products

As a precautionary measure, keep away from strong oxidizers.

8. Exposure controls/personal protection

Control parameters

Exposure guidelines

The exposure guidelines listed below are for the individual components and not the product itself.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Oxycodone Hydrochloride	Not Available	Not Available	Not Available
Sorbitol	Not Available	Not Available	Not Available
Citric Acid	10 mg/m ³ TWA	15 mg/m ³ TWA	Not Available
Sodium Citrate	Not Available	Not Available	Not Available
Sodium Benzoate	Not Available	Not Available	Not Available
Saccharin Sodium	Not Available	Not Available	Not Available
FD&C Red #40	Not Available	Not Available	Not Available
Artificial Raspberry Flavor	Not Available	Not Available	Not Available

Appropriate engineering controls

Engineering measures

Engineering controls should be used to limit exposure. Ventilation should be matched to conditions.

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Individual protection measures, such as personal protective equipment

Eye/face protection None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full-face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Skin protection

Hand protection For consumer use, no unusual precautions are necessary.

Other None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

Respiratory protection None required for consumer use. 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 exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.

Hygiene measures Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state Solution
 Appearance Clear, red solution, free of sedimentation
 Odor Not available.
 Odor threshold Not available.

Property	Values	Remarks/Method
pH	1.4 – 4.6	
Melting point/range	Not available.	
Boiling point/boiling range	Not available.	
Flash point	Not available.	
Evaporation rate	Not available.	
Flammability (solid, gas)	Not available.	
Flammability limits in air	Not available.	
-upper flammability limit	Not available.	
-lower flammability limit	Not available.	
Vapor pressure	Not available.	
Vapor density	Not available.	
Specific gravity	Not available.	
Water solubility	Not available.	

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Solubility in other solvents	Not available.
Partition coefficient: n-octanol/water	Not available.
Autoignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Flammable properties	Not available.
Explosive properties	Not available.
Oxidizing properties	Not applicable

Other information

VOC content (%) Not applicable

10. Stability and reactivity

Reactivity The product is non-reactive under normal conditions of use, storage, and transport

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials. Exposure to light.

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

Hazardous decomposition products No Hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation Not expected to be hazardous in final pharmaceutical form.

Eye contact Not expected to be hazardous in final pharmaceutical form. Contact with eyes may cause temporary irritation.

Skin contact Not expected to be hazardous in final pharmaceutical form.

Ingestion Ingestion may cause irritation and malaise.

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Information on toxicological effects

Acute toxicity May be harmful if swallowed in large quantities.

The information in the table below is for the individual components and not the product.

Component	LD50 oral	LD50 dermal	LC50 inhalation
Oxycodone Hydrochloride	oxycodone: 482 mg/kg mouse	Not Available	Not Available
Sorbitol	Not Available	Not Available	Not Available
Citric Acid	5400 mg/kg Rat	>2000 mg/kg Rabbit	Not Available
Sodium Citrate	Not Available	Not Available	Not Available
Sodium Benzoate	2100 mg/kg Rat	Not Available	Not Available
Saccharin Sodium	14200 mg/kg Rat	Not Available	Not Available
FD&C Red #40	>10000mg/kg Rat	>10000 mg/kg Rabbit	Not Available
Artificial Raspberry Flavor	Not Available	Not Available	Not Available

Symptoms related to the physical, chemical and toxicological characteristic

Respiratory depression is the chief hazard. Trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

Delayed and immediate effects and also chronic effects from short and long term exposure

Sensitization	No data available
Mutagenic effects	Oxycodone hydrochloride was genotoxic in an in vitro mouse lymphoma assay in the presence of metabolic activation. There was no evidence of genotoxic potential in an in vitro bacterial reverse mutation assay (<i>Salmonella typhimurium</i> and <i>Escherichia coli</i>) or in an assay for chromosomal aberrations (<i>in vivo</i> mouse bone marrow micronucleus assay).
Carcinogenicity	Long-term animal studies to evaluate the carcinogenic potential of oxycodone have not been conducted.
Reproductive toxicity	The potential effects of oxycodone on male and female fertility have not been evaluated..
STOT – single exposure	Narcotic effects.
STOT – repeated exposure	Not classified.
Aspiration hazard	Not classified.
Numerical measures of toxicity	No data available.

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12. Ecological information

Ecotoxicity	This product is not classified as environmentally hazardous.
Persistence and Degradability	No data available
Bioaccumulation	No data available
Other adverse effects	None

The following table lists the data for the individual components, if available.

Chemical name	Toxicity to algae	Toxicity to fish	Toxicity to micro-organisms	Daphnia Magna (water flea)
Oxycodone Hydrochloride	Not Available	Not Available	Not Available	Not Available
Sorbitol	Not Available	Not Available	Not Available	Not Available
Citric Acid	Not Available	440 mg/L 48 hr. Leuciscus idus melanotus	Not Available	1535 mg/L 24 hr.
Sodium Citrate	Not Available	Not Available	Not Available	Not Available
Sodium Benzoate	Not Available	484 mg/L 96 hr. Pimephales Promelas	Not Available	Not Available
Saccharin Sodium	Not Available	Not Available	Not Available	Not Available
FD&C Red #40	Not Available	Not Available	Not Available	Not Available
Artificial Raspberry Flavor	Not Available	Not Available	Not Available	Not Available

13. Disposal considerations

Waste disposal methods	Dispose of waste in accordance with all federal, state and local regulations. In the U.S., oxycodone hydrochloride is a Schedule II controlled substance and may have additional requirements for proper disposal. Empty containers may retain some product residues. This material and its container must be disposed of in a safe manner.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since empties containers may retain product residue, follow label warning even after container is emptied.

14. Transport information

Notes:

Not regulated as a dangerous good under USDOT, IATA, TDG, IMDG or other regulations.

Transport in bulk according to Annex II of MARPOL 73/78 and IBC Code

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15. Regulatory information

US federal regulations

This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

Over-the-counter drugs in their solid final form (i.e. tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.

DEA: Oxycodone Hydrochloride Oral Solution, CII is a DEA scheduled II controlled substance.

FDA: Oxycodone Hydrochloride Oral Solution, CII is an approved prescription medication

US TSCA Section 12(b) Not listed.

US CERCLA Status Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Immediate Hazard	Yes
Delayed Hazard	No
Fire Hazard	No
Pressure Hazard	No
Reactivity Hazard	No

US SARA 302 Not listed.

US SARA 311/312 Not a hazardous chemical.

US SARA 313 Not listed.

US PROP 65 (calif.) Not listed.

US EPA label information Not applicable.

OSHA specifically Regulated Substances Not listed.

Clean Water Act Not regulated. (40 CFR 122.21 and 40 CFR 122.42)

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U.S. state Right-to-Know regulations

"X" designates that the ingredients are listed on the state Right-to-Know list

Chemical name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Oxycodone Hydrochloride					
Sorbitol	X		X		
Citric Acid	X		X		
Sodium Citrate	X		X		
Sodium Benzoate	X	X	X		
Saccharin Sodium					
FD&C Red #40					
Artificial Raspberry Flavor	X		X		

International inventories

Country(s) or region	Inventory name	On inventory list (yes/no)*
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No

*A "Yes" indicates this product complies 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

Prepared by: Pharmaceutical Associates Regulatory Affairs Department
 Issuing date: 22FEB2018
 Revision date: 15JUL2019
 Revision note: **Revision 00**
 Original SDS Created
Revision 01
 Added NDC Number 0121-4827-40

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General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet