



SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION

Product Identification:

Oxycodone Hydrochloride (CII) Oral Solution, 100 mg / 5 mL, 30 mL bottle	NDC 64950-353-03
Oxycodone Hydrochloride (CII) Oral Solution, 5 mg / 5 mL, 5 mL cup	NDC 64950-354-05
Oxycodone Hydrochloride (CII) Oral Solution, 5 mg / 5 mL, 100 mL bottle	NDC 64950-354-10
Oxycodone Hydrochloride (CII) Oral Solution, 5 mg / 5 mL, 5 mL cup, 40 ct	NDC 64950-354-45
Oxycodone Hydrochloride (CII) Oral Solution, 5 mg / 5 mL, 500 mL bottle	NDC 64950-354-50
Oxycodone Hydrochloride (CII) Oral Solution, 5 mg / 5 mL, 5 mL cup, 50 ct	NDC 64950-354-55
Oxycodone Hydrochloride (CII) Prefilled Oral Dispenser, 10 mg / 0.5 mL, 0	NDC 64950-353-01
Oxycodone Hydrochloride (CII) Prefilled Oral Dispenser, 20 mg / mL,	NDC 64950-353-02
Oxycodone Hydrochloride (CII) Prefilled Oral Dispenser, 10 mg / 0.5 mL, , case of 50	NDC 64950-353-51
Oxycodone Hydrochloride (CII) Prefilled Oral Dispenser, 20 mg / mL, , case of 50	NDC 64950-353-52
Oxycodone Hydrochloride (CII) Prefilled Oral Dispenser, 10 mg / 0.5 mL, , 1 pouch of 5 Prefilled Oral Dispensers	NDC 64950-353-91
Oxycodone Hydrochloride (CII) Prefilled Oral Dispenser, 20 mg / ml, 0.5 mL, 1 pouch of 5 Prefilled Oral Dispensers	NDC 64950-353-92

Recommended use:

Oxycodone Hydrochloride (HCl) CII Oral Solution is an immediate release oral formulation of Oxycodone HCl indicated for the management of moderate to severe acute and chronic pain where the use of an opioid analgesic is appropriate and a continuous, around-the-clock analgesic is needed for an extended period of time. Oxycodone HCl OS is intended for oral use only. Reserve Oxycodone HCl OS for use in patients for whom alternative treatment options have not been tolerated or are not expected to be tolerated, and/or have not provided adequate analgesia or are not expected to provide adequate analgesia.

Restrictions:

Oxycodone HCl OS is contraindicated in patients with known hypersensitivity to Oxycodone or in situations where opioids are contraindicated. It's also contraindicated in patients with significant respiratory depression, and acute or severe bronchial asthma. It can cause the breathing problems and the blood pressure to drop. Abuse of Oxycodone HCl poses a risk of overdose and death. The risk is increased with concurrent abuse of alcohol and other substances.

Manufacturer Name:

Genus Lifesciences Inc.



Manufacturer Address: 514 N. 12th Street
Allentown, PA 18102

Telephone number: (610) 782-9780 ext.*100
Fax number: (610) 782-9781

SECTION 2 – HAZARD (S) IDENTIFICATION

Classification (GHS):

The product Oxycodone Hydrochloride (HCl) CII Oral Solution is a non-hazardous pharmaceutical mixture and does not meet OSHA's Hazard Communication Standard (HCS) 2012, 29 CFR 1910.1200 and OSHA's Globally Harmonized System (GHS) hazard criteria. As per OSHA section 1910.1200(b)(6)(vii), "Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient; drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment" are exempt. The GHS hazards listed below are for the active product ingredient (API), Oxycodone HCl CII, and not for the OS product itself.

Physical hazards: Not classified

Health hazards: Acute Toxicity Oral Category 4
Specific Target Organ Toxicity, Single Exposure Category 3 Narcotic Effects

Environmental hazards: Not classified

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. This product is a DEA Schedule II controlled substance. Substances in the DEA Schedule II have a high potential for abuse which may lead to severe psychological or physical dependence.

Pictogram:



Precautionary Statement: May cause drowsiness or dizziness. In large quantities it may be harmful if swallowed or thru skin absorption; or may cause an allergic skin reaction.

Hazards Not Otherwise Classified: None known.

SECTION 3 – COMPOSITION / INFORMATION OF INGREDIENTS*



Chemical Identity	Other Names	CAS Number
Citric Acid Anhydrous	None	77-92-9
D&C Yellow #10	None	8004-92-0
FD&C Red # 40	Allura	25956-17-6
Natural / Artificial Berry Flavor	N/A	N/A
Oxycodone HCl (Active Ingredient)	None Available	124-90-3
Purified Water	None	7732-18-5
Saccharin Sodium	Sodium saccharine, Soluble saccharin, Sweeta	82385-42-0
Sodium Benzoate	E211, Benzoate of Soda	532-32-1
Sodium Citrate Dihydrate	Citric acid trisodium salt, Trisodium citrate dihydrate	6132-04-3
Sorbitol Solution 70%	Glucitol, D-glucitol; D-Sorbitol; Sorbogem; Sorbo	50-70-4

* Chemical exact percentage (concentration) of composition has been withheld as a trade secret.

SECTION 4 – FIRST AID MEASURES

- Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Remove contact lenses if worn. Seek medical attention if irritation or discomfort persists.
- Skin Contact:** Wash with soap and large amount of water. Contact medical personnel if irritation persists.
- Ingestion:** This product is intended for ingestion. If an overdose, taken not as prescribed, or an accidental ingestion of large amounts occurs, call a physician immediately.
- Inhalation:** Not an expected route of exposure. If breathing is difficult, move to fresh air and seek medical attention.
- Symptoms or effects:** The most common side effects include nausea, constipation, vomiting, headache, and pruritus. The frequency of these reactions depended on several factors, including clinical setting, the patient's level of opioid tolerance, and host factors specific to the individual.
- Recommendations:** Immediate medical attention is required if an overdose is suspected. Call a Poison Control Center (1-800-222-1222) if you feel unwell.
- Note to Physician:** Oxycodone is a pure opioid agonist with an analgesic potency about twice that of morphine. Naloxone is a specific antidote against respiratory depression from opioid overdose. Opioid antagonists should not be administered in the absence of clinically significant respiratory or circulatory depression secondary to oxycodone overdose. Primary attention should be given to the re-establishment of a patient airway and institution of assisted or controlled ventilation. Supportive measures 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. If ingested and the patient is conscious, induction of emesis may be indicated. Gastric lavage may be indicated if the patient is unconscious.

SECTION 5 – FIREFIGHTING MEASURES

Extinguishing media	Use Water, Dry chemical, CO ₂ or any material appropriate for fire in the surrounding area. Do not use water jet as an extinguisher, as this might spread the fire.
Specific hazards arising from the mixture:	None known, however gases hazardous to health might be formed (Refer to section 10)
Advice to the firefighters:	Wear appropriate protective clothing and equipment, including self-contained breathing apparatus.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Clean the spill if is safe to do so. Minimize exposure.
Protective Equipment:	Safety Glasses or goggles, gloves, protecting clothes. (Refer to section 10)
Emergency procedures:	Evacuate the area. Keep unnecessary personnel away. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.
Containment Precautions:	Isolate area around spill as specified by site procedures.
Clean Up Procedures:	Use suitable absorbent material. Collect the material in a compatible container. Dispose according to applicable regulations (Refer to section 13). Decontaminate with water.

SECTION 7 – HANDLING AND STORAGE

Precaution for safe handling:	Observe safe industrial practices. No special handling requirements for normal use of this material. Dispense content with a child resistant closure and in a tight, light-resistant container as defined in the USP/NF.
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Conditions for safe storage: Store at Controlled Room Temperature at 25°C (77°F), excursions are permitted to 15° - 30°C (59° - 86°F). Protect from Moisture and Light. Keep container tightly closed. Keep out of reach of children. Do not use if seal under cap is missing or broken. For more information follow directions in product packaging.

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

There is no exposure limits for the Oxycodone HCl (CII) OS products. The exposure limits listed below are for the active product ingredient (API) Oxycodone HCl CII and not for the Oral Solution (OS) product itself.

OSHA Permissible Exposure Limits (PELs):	None
Occupational Exposure Limit (OEL's):	30 µg/m ³
Acceptable Daily Exposure (ADE):	170 µg/day
5 Band System Exposure Classification:	Category 2 – Moderate
ACGIH Threshold Limit Values (TLVs):	
Short Term Exposure Limits (STEL) – 15 min:	Not Available
Time Weight Average (TWA) – 8 Hours:	0.5 ppm
NIOSH Immediately Dangerous to Life or Health (IDLH):	None

Engineering Controls: Not required when handling liquid or containers. Good ventilation should be use. Ventilation should be matched to conditions.

Personal Protective Measures:

Respiratory protection:	None required when handling liquids.
Eye protection:	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Protective gloves:	Not required under normal conditions of use. Chemical compatible when needed.
Skin and body protection:	Not required under normal conditions of use.
Hygiene measures:	Wash hands thoroughly.
Other personal protection:	None required



SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Appearance:

Dose	Description
100 mg / 5 ml	Clear yellow berry flavor
5 mg / 5 ml	Clear red berry flavor

Odor:	Berry	Density:	Not Available
Boiling Point:	Not available	Melting Point:	Not Applicable
Solubility:	In water	Viscosity:	Not Available
Specific Gravity:	Not Available	Evaporation Rate:	Not Available
Conductivity:	Not Available		

Chemical Properties:

pH:	3.0 to 4.0	Flash Point:	Not Available
Reactivity:	Refer to section 10	Toxicity:	Refer to section 11

SECTION 10 – STABILITY AND REACTIVITY

Reactivity: None expected under normal conditions of use.

Chemical stability: Stable under normal conditions of use.

Other:

Conditions to avoid:	Moisture and light.
Incompatible materials:	As a precautionary measure, keep away from strong oxidizers.
Hazardous decomposition products:	None known

SECTION 11 – TOXICOLOGICAL INFORMATION

Routes of exposure: Ingestion



Delayed, immediate and chronic effects for short and long term exposure:

General effects:	Possible effects are gastrointestinal adverse reactions, hypotension, adrenal insufficiency, addiction, abuse, and misuse. Rapid tapering of Oxycodone HCl OS in a patient physically dependent on opioids may lead to a withdrawal syndrome and return of pain.	
Sensitization:	Not a respiratory sensitizer	
Mutagenic effects:	Oxycodone is not mutagenic	
Reproductive toxicity:	No adverse effect in fertility. Neonatal withdrawal after maternal use has occurred. Oxycodone is excreted into human breast milk.	
Fetotoxic / Teratogenic Effects:	Oxycodone is not teratogenic or fetotoxic.	
Specific Target Organ Toxicity (STOT):	Single exposure:	Not Classified
	Repeated exposure:	Not Classified

Toxicity (LD50):

Toxicity studies have not been conducted with the Oxycodone HCl (CII) OS products. The exposure limits listed below are for the active product ingredient (API) Oxycodone HCl CII and not for the Oral Solution (OS) product itself.

Subcutaneous LD ₅₀ Rat:	426 mg/kg
Intraperitoneal (IP) LD ₅₀ Mouse:	320 mg/kg

Symptoms / Adverse Reactions:

The common adverse reactions seen on initiation of therapy with Oxycodone HCl OS are dose-related and are typical opioid-related adverse reactions. The most frequent adverse events include nausea, constipation, vomiting, headache, and pruritus. The frequency of these reactions depended on several factors, including clinical setting, patient's level of opioid tolerance, and host factors specific to the individual.

Serious adverse reactions associated with Oxycodone HCl OS use include respiratory depression, respiratory arrest, circulatory depression, cardiac arrest, hypotension, and/or shock.

Carcinogenicity:

Not listed as a carcinogen by OSHA. Long term carcinogenicity studies have not been conducted.



SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity (Toxicity effects):	Environmental properties have not been thoroughly evaluated for the product. Releases to the environment should be avoided.
Persistence and Degradability:	No data available
Bioaccumulation:	No data available
Leaching studies:	Not Available. Expected to be slightly too moderately mobile in soil.
Other adverse effects:	The pharmaceutical product is not classified as environmentally hazardous. No major harmful effects to aquatic organisms are expected, however; is highly recommended to avoid environmental releases.

SECTION 13 – DISPOSAL INFORMATION

Disposal Containers:	Dispose used or contaminated containers in accordance with Drug Enforcement Administration (DEA) guidelines and the federal, state or local regulatory requirements.
Waste Disposal Methods:	Dispose of waste in accordance with Drug Enforcement Administration (DEA) guidelines and the federal, state or local regulatory requirements.
Special Precautions:	Discard away from children's reach. Releases to the sewer should be avoided.

SECTION 14 – TRANSPORT INFORMATION

USDOT - Department of Transportation:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under USDOT.

ICAO - International Civil Aviation Organization:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under ICAO.



IATA - International Air Transport Association:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under IATA.

IMDG/IMO - International Maritime Dangerous Goods / International Maritime Organization:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under IMDG/IMO.

Special Precautions: None Known

SECTION 15 – REGULATORY INFORMATION

Drug Enforcement Administration (DEA): Listed as Schedule II Controlled Substances (CII).

Food and Drug Administration (FDA): Approved prescription medication.

Occupational Safety and Health Administration (OSHA):

GHS symbols in consumer packaged form are not required per OSHA 29 CFR 1910.1200(b)(5) and OSHA 29 CFR 1910.1200(b)(5)(iii).

SARA 302/304 Extreme Hazardous Substances (EHS): Not Listed

SARA 311/312 Hazard Categories: Immediate Hazard – No
Delayed Hazard – No
Fire Hazard – No
Pressure Hazard – No
Reactivity Hazard – No

SARA 313 Toxic Chemical Release Inventory (TRI): Not Regulated

Resource Conservation and Recovery Act (RCRA): No Code Applicable

Clean Water Act (CWA):

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).



Clean Air Act (CAA):

This product does not contain any chemicals listed under Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

Toxic Substances Control Act (TSCA):

Not applicable for the product. The following ingredients are included on the TSCA inventory 8(b):

Ingredient	CAS No
Citric Acid Anhydrous	77-92-9
D&C Yellow #10	8004-92-0
FD&C Red # 40	25956-17-6
Purified Water	7732-18-5
Propylparaben	94-13-3
Sodium Benzoate	532-32-1
Sorbitol Solution	50-70-4

Environmental Response Compensation and Liability Act (CERCLA):

Not applicable for the product. This product, as supplied, do not contains substances regulated as hazardous substances under CERCLA (40 CFR 302). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

SECTION 16 – OTHER INFORMATION

See current package insert for further information.

SDS prepared by Genus Lifesciences Inc.

Creation Date: Jul/11/14, New SDS

Revision Date: Jul/20/21

This Safety Data Sheet cancels and replaces all preceding SDS for this product.

Genus Lifesciences Inc. believes that the information contained herein is based on the best available data at the date of preparation. However, no warranty is expressed or implied regarding the data's accuracy and completeness. Since the use of this information and the conditions of use of this material are not within the control of Genus Lifesciences Inc., it is the user's obligation to determine the conditions of safe use of this material.

Signature Manifest

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SDS Oxycodone HCl OS - 64950

Department Approval

Name/Signature	Title	Date	Meaning/Reason
July Ortiz (JORTIZ)		11 Aug 2021, 03:07:33 PM	Approved

Regulatory Affairs Approval

Name/Signature	Title	Date	Meaning/Reason
Bill Reightler (BREIGHTLER)		11 Aug 2021, 04:11:49 PM	Approved

Quality Assurance Approval

Name/Signature	Title	Date	Meaning/Reason
Rama Chitirala (RCHITIRALA)	QA Director	13 Aug 2021, 03:41:02 PM	Approved