SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION

Product Identification:

Oxycodone Hydrochloride (CII) Capsule, 5mg, 100 count bottle	NDC 64950-901-10

Recommended use and restrictions: Oxycodone Hydrochloride is a product used as opioid analgesic indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

Oxycodone HCl Capsule is contraindicated in patients with known hypersensitivity to oxycodone, or in any situation where opioids are contraindicated. It can cause the blood pressure to drop and breathing problems.

Oxycodone hydrochloride is intended for oral use only. Abuse of oxycodone hydrochloride 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

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

SECTION 2 – HAZARD (S) IDENTIFICATION

Classification of the substance or mixture (GHS):

Pictogram: 

Signal Word: Warning

Hazard Statement: When used and handled according to indications, the product does not have any harmful effects. Accidental ingestion of large amounts may be fatal. Constant use might cause substance dependence.

SECTION 3 – COMPOSITION / INFORMATION OF INGREDIENTS

Chemical Identity	Other Names	CAS Number
Colloidal Silicone Dioxide, NF	Fumed Silica	99439-28-8
Hard Gelatin Capsule Size #4	N/A	N/A
Lactose Anhydrous, NF	Supertab 22 AN	63-42-3
Magnesium Stearate, NF	Magnesium Octadecanoate	557-04-0
Microcrystalline Cellulose, NF	PH 102, Cellulose Gel	9004-34-6
Oxycodone HCl (Active Ingredient)	N/A	124-90-3
Pregelatinized starch, NF	Starch 1500	9057-07-2
Sodium Lauryl Sulfate, NF	Kolliphor, Sodium Dodecyl Sulfate	151-21-3
Sodium Starch Glycolate, NF	N/A	9063-38-1

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.

Skin Contact: Wash with soap and large amount of water. Seek medical attention.

Ingestion: If an accidental ingestion of large amounts occur, call a physician or poison control center immediately.

Inhalation: Should not pose a hazard. If breathing is difficult, move to fresh air and seek medical attention.

Note to Physicians: 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 carbon dioxide, dry chemical, water spay, or any material appropriate for fire in the surrounding area.
Fire / Explosion Hazards:	Not Applicable.
Advice to the firefighters:	Wear self-contained breathing apparatus for the firefighting and full protective clothing.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

Exposure Limits:	Not Available
Respiratory Protection:	Not required
Personal Protection:	Personnel should wear appropriate personal protective equipment and minimize exposure.

Methods and Materials for containment and clean up:

Use appropriate personal protective equipment. Contain the source if is safe to do so. Dispose according to applicable regulations. Incineration of the waste at an approved facility is recommended.

SECTION 7 – HANDLING AND STORAGE

Precaution for safe handling:	Observe safe industrial practices. Avoid contact with eyes, skin, and clothing. Use with adequate ventilation.
Conditions for safe storage:	To maintain potency, store capsules in the original container with the child resistant closure tightly secured. Protect from light. Store in a dry area at room temperature (25°C / 77°F). Keep out of reach of children. For more information follow as directed in product packaging.

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection:	Not required when handling liquid or containers. If it found to be necessary, wear appropriate NIOSH approved respirator.
Ventilation:	Handle material under adequate ventilation.
Protective gloves:	Chemical compatible
Eye protection:	Safety glasses or goggles
Other personal protection:	Consult a safety professional for additional guidance, as needed.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Opaque yellow cap and opaque white body imprinted LV on the cap and 901 on the body in black ink

Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solubility:	In water up to 0.18 g / ml	Odor:	None

SECTION 10 – STABILITY AND REACTIVITY

Chemical stability:	Stable under normal conditions of use.
Conditions to avoid:	Excessive heat, light, and moisture.
Incompatible materials:	Strong oxidizers, acids, bases
Hazardous decomposition:	Will not occur.

SECTION 11 – TOXICOLOGICAL INFORMATION

Carcinogenicity: Not listed as a carcinogen by OSHA

Routes of exposure: Ingestion – Ingestion may cause irritation.
Inhalation – Not expected to be hazardous in final pharmaceutical form.

Symptoms related to the toxicological characteristics: Nausea, vomiting, dizziness and somnolence.

Acute toxicity: May be harmful if swallowed in large quantities

SECTION 12 – ECOLOGICAL INFORMATION

The product is not classified as environmentally hazardous. No data is available on the degradability of this product.

SECTION 13 – DISPOSAL INFORMATION

Dispose of waste in accordance with the Drug Enforcement Administration (DEA) guidelines and federal, state and local regulations.

SECTION 14 – TRANSPORT INFORMATION

This product is not regulated for the safe transport of hazardous chemicals under USDOT regulations.

SECTION 15 – REGULATORY INFORMATION

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.

OSHA GHS: 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).

Drug Enforcement Administration (DEA):	Schedule II Controlled Substance
Federal Drug Administration (FDA):	Approved prescription medication

SECTION 16 – OTHER INFORMATION

See current package insert for further information.

SDS prepared by Genus Lifesciences Inc.

Issue Date: Jun/15/15, New SDS

Revision Date: Jul/06/2017

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