# SAFETY DATA SHEET

## SECTION 1 - IDENTIFICATION

**Product Identification:**

| | |
|---|---|
| Phenobarbital Tablets USP, (CIV), 15 mg, 100 ct Bottle | NDC 64950-571-01 |
| Phenobarbital Tablets USP, (CIV), 15 mg, 1000 ct Bottle | NDC 64950-571-10 |
| Phenobarbital Tablets USP, (CIV), 16.2 mg, 100 ct Bottle | NDC 64950-572-01 |
| Phenobarbital Tablets USP, (CIV), 16.2 mg, 1000 ct Bottle | NDC 64950-572-10 |
| Phenobarbital Tablets USP, (CIV), 30 mg, 100 ct Bottle | NDC 64950-573-01 |
| Phenobarbital Tablets USP, (CIV), 30 mg, 1000 ct Bottle | NDC 64950-573-10 |
| Phenobarbital Tablets USP, (CIV), 32.4 mg, 100 ct Bottle | NDC 64950-574-01 |
| Phenobarbital Tablets USP, (CIV), 32.4 mg, 1000 ct Bottle | NDC 64950-574-10 |
| Phenobarbital Tablets USP, (CIV), 60 mg, 100 ct Bottle | NDC 64950-575-01 |
| Phenobarbital Tablets USP, (CIV), 60 mg, 1000 ct Bottle | NDC 64950-575-10 |
| Phenobarbital Tablets USP, (CIV), 64.8 mg, 100 ct Bottle | NDC 64950-576-01 |
| Phenobarbital Tablets USP, (CIV), 64.8 mg, 1000 ct Bottle | NDC 64950-576-10 |
| Phenobarbital Tablets USP, (CIV), 97.2 mg, 100 ct Bottle | NDC 64950-577-01 |
| Phenobarbital Tablets USP, (CIV), 97.2 mg, 1000 ct Bottle | NDC 64950-577-10 |
| Phenobarbital Tablets USP, (CIV), 100 mg, 100 ct Bottle | NDC 64950-578-01 |
| Phenobarbital Tablets USP, (CIV), 100 mg, 1000 ct Bottle | NDC 64950-578-10 |

**Product Name:** Phenobarbital Tablets USP, (CIV)

**Recommended use:** Phenobarbital CIV is a tablet that is given to control epilepsy in humans only. It can be used as a lone therapy or along with other drugs to decrease the frequency and severity of the patience's seizures. It works by controlling the abnormal electrical activity in the brain that occurs during a seizure. This medication is also used for a short time (usually no more than 2 weeks) to help the patience to be calm and/or to sleep during periods of anxiety. It works by affecting certain parts of the brain to cause calming.

**Restrictions:** Use with caution when giving to patience's with Addison's disease, kidney disease, liver disease, respiratory abnormalities, or anemia. Phenobarbital CIV may interact with other drugs so it's best to consult with a doctor if the patience is on other medication.

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**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 Phenobarbital CIV Tablets is a non-hazardous pharmaceutical mixture and does not meet OSHA's Hazard Communication Standard (HCS) 2012, 29CFR 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), Phenobarbital CIV, and not for the Tablet product itself.

| | |
|---|---|
| Physical hazards: | Not classified |
| Health hazards: | Acute Toxicity Oral Category 3<br>Skin Sensitization Category 1<br>Carcinogenicity Category 2<br>Reproduction Toxicity (Fertility and unborn child) Category 1B<br>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 IV controlled substance. Substances in the DEA Schedule IV have a low potential for abuse and low risk of dependence.

**Pictogram:**



**Precautionary Statement:** Phenobarbital may be habit forming. Tolerance, psychological and physical dependence may occur with continued use. Phenobarbital is a barbiturate. Barbiturates are depressants that produce a wide spectrum of central nervous

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system depression from mild sedation to coma. Barbiturates can be extremely dangerous because overdoses can occur easily and lead to death. Read label before use.

**Hazards Not Otherwise Classified:** None known.

## SECTION 3 – COMPOSITION / INFORMATION OF INGREDIENTS*

| Chemical Identity | Other Names | CAS Number |
|---|---|---|
| Colloidal Silicon Dioxide, NF | Cab-O-Sil, Quartz, Dioxosilane | 7631-86-9 |
| Lactose Monohydrate, NF | SuperTab 11SD | 64044-51-5 |
| Magnesium Stearate, NF | N/A | 557-04-0 |
| Microcrystalline Cellulose, NF | Avicel PH102 | 9004-34-6 |
| Phenobarbital, USP (Active Ingredient) | N/A | 50-06-6 |
| Sodium Starch Glycolate, NF | Explotab | 9063-38-1 |

* 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:** Narcotic effects. The most common side effects include mild euphoria, lack of restraint, relief of anxiety, and sleepiness. Higher doses might cause impairment of memory, judgement, and coordination; irritability, paranoia, and suicidal ideation. An overdose will cause decreased respiration, blood pressure, urine production, body temperature; increased heart rate, and in some cases coma and possible death. After prolonged use, it may cause significant liver impairment.

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**Recommendations:** Immediate medical attention is required if an overdose is suspected. Call a Poison Control Center (1-800-222-1222) or 911 if you feel unwell. No action shall be taken involving any personal risk or without suitable training. If needed and if possible, give artificial respiration and/or CPR. Do **NOT** induce vomiting due to potential CNS depression. Administer activated charcoal as slurry.

**Note to Physician:** Phenobarbital is a barbiturate that is abused by swallowing pills or injecting a liquid form. Barbiturates are generally abused to reduce anxiety, decrease inhibitions, and treat unwanted effects of illicit drugs. Provide general supportive measures and treat symptomatically. In severely poisoned patients, consider multiple doses of activated charcoal. Cathartics are **NOT** recommended. Urinary alkalization may enhance clearance of Phenobarbital. For hypotension, infuse isotonic fluid. If hypotension persists, administer dopamine or norepinephrine.

For patients with hemodynamic compromise refractory to aggressive supportive care, consider hemodialysis or charcoal hemoperfusion to enhance elimination. Monitor vital signs and fluid balance. Maintain adequate airway with assisted respiration and administration of oxygen. Maintain blood pressure and body temperature. For shock, administer fluid therapy or other standard treatment. **AVOID** fluid or sodium overload.

Take appropriate care to prevent hypostatic pneumonia, decubiti, aspiration, and other complications of altered states of consciousness. For pneumonia, take appropriate cultures and administer antibiotics. Chest physiotherapy should be administered. The exposed person may need to be kept under medical surveillance for 48 hours.

## 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:** No action shall be taken involving any personal risk or without suitable training. Clean the spill if is safe to do so. Minimize exposure. Keep unnecessary personnel away. Do not touch or walk through spilled material.

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**Protective Equipment:** Safety Glasses or goggles, gloves, protecting clothes. (Refer to section 8)

**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.

**Conditions for safe storage:** Store in original container, at a locked 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 are no exposure limits for the Phenobarbital CIV Tablets products. The exposure limits listed below are for the active product ingredient (API) Phenobarbital CIV and not for the Tablets product itself.

| | |
|---|---|
| OSHA Permissible Exposure Limits (PELs): | None |
| Occupational Exposure Limit (OEL's): | 10 µg/m$^3$ |
| Acceptable Daily Exposure (ADE): | 30 µg/day |
| 5 Band System Exposure Classification: | Category 3 – High |
| ACGIH Threshold Limit Values (TLVs): | |
| Short Term Exposure Limits (STEL) – 15 min: | Not Available |

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| | |
|---|---|
| Time Weight Average (TWA) – 8 Hours: | Not Available |
| NIOSH Immediately Dangerous to Life or Health (IDLH): | None |

**Engineering Controls:** Not required when handling tablets or containers. Ventilation should match conditions.

**Personal Protective Measures:**

| | |
|---|---|
| Respiratory protection: | None required when handling tablets. If it found to be necessary, wear a mask or an appropriate NIOSH approved respirator. |
| 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, forearms and face thoroughly after handling chemical products, before eating and at the end of working period. Contaminated work clothing should not be allowed out of the workplace. Wash clothing before reusing. |
| Other personal protection: | None required |

## SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

**Physical Properties:**

| | | | |
|---|---|---|---|
| Appearance: | Round White Tablets | Odor: | Odorless |
| Density: | Not Available | Boiling Point: | Not available |
| Melting Point: | Not Applicable | Solubility: | Water, Alcohol |
| Viscosity: | Not Available | Specific Gravity: | Not Available |
| Evaporation Rate: | Not Available | Conductivity: | Not Available |

**Chemical Properties:**

| | | | |
|---|---|---|---|
| pH: | Not Available | Flash Point: | Not Available |
| Reactivity: | Refer to section 10 | Toxicity: | Refer to section 11 |

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## 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 heat.

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: Narcotic effects, dizziness, drowsiness, vertigo, headache, lethargy, incoordination, weakness, slurred speech, uncontrolled eye movement, confusion, anxiety, fever, restlessness, impaired judgment, sore throat, insomnia, nightmares, depression, bruising, gastrointestinal disturbances.

Sensitization: Active ingredient is a skin sensitizer. An allergic skin reaction may occur when exposed to some levels.

Mutagenic effects: No known significant effects or critical hazards.

Reproductive toxicity: Active ingredient is suspected of damaging fertility. Therapeutic use during the last trimester of pregnancy may cause physical dependence and withdrawal in the newborn. Barbiturates are distributed into the milk of nursing women; nursing should be discontinued if using the product.

Fetotoxic / Teratogenic Effects: Active ingredient is suspected of damaging the unborn child. Some barbiturates have been shown to cause an increased incidence of fetal abnormalities.

Specific Target Organ Toxicity (STOT):

Single exposure: Narcotic effects

Repeated exposure: There is no data available.

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**Toxicity (LD50):**

Toxicity studies have not been conducted with the Phenobarbital CIV Tablets products. The exposure limits listed below are for the active product ingredient (API) Phenobarbital CIV and not for the Tablets product itself.

| | | | |
|---|---|---|---|
| Oral $LD_{50}$ Rat: | 162 mg/kg | Subcutaneous (SC) $LD_{50}$ Rat: | 200 mg/kg |
| Intraperitoneal (IP) $LD_{50}$ Rat: | 110 mg/kg | Intravenous (IV) $LD_{50}$ Rat: | 209 mg/kg |
| Rectal $LD_{50}$ Rat: | 284 mg/kg | Oral $LD_{50}$ Mouse: | 137 mg/kg |
| Subcutaneous $LD_{50}$ Mouse: | 228 mg/kg | Intravenous (IV) $LD_{50}$ Mouse: | 218 mg/kg |
| Intramuscular $LD_{50}$ Mouse: | 175 mg/kg | Intraperitoneal $LD_{50}$ Mouse: | 88 mg/kg |
| Oral $LD_{50}$ Rabbit: | 185 mg/kg | Intravenous (IV) $LD_{50}$ Rabbit: | 187 mg/kg |
| Oral $LD_{50}$ Dog: | 150 mg/kg | Oral $LD_{50}$ Guinea Pig: | 130 mg/kg |

**Symptoms / Adverse Reactions:** The common adverse reactions seen are hangover, drowsiness, lethargy, vertigo, phobia, allergic reactions, swelling, fever, nausea, vomiting, and headache. Serious adverse reactions include respiratory depression, apnea, and circulatory collapse.

**Carcinogenicity:** Product not listed as a carcinogen by OSHA. API is suspected of causing cancer. Risk of cancer depends on duration and level of exposure.

## SECTION 12 – ECOLOGICAL INFORMATION

**Ecotoxicity (Toxicity effects):**

Ecotoxicity studies have not been conducted with the Phenobarbital CIV Tablets products. The exposure limits listed below are for the active product ingredient (API) Phenobarbital CIV and not for the Tablets product itself.

| | |
|---|---|
| $LC_{50}$ Daphnia magna (Water flea): | 1,460 mg/L for 24 hrs. |
| $LC_{50}$ Pimephales promelas Fish (Fathead minnow): | 484 mg/L for 96 hrs. |

**Persistence and Degradability:** If released to air, an estimated vapor pressure of $1.4X10^{-11}$ mm Hg at 25 °C indicates that Phenobarbital will exist solely in the particulate phase in the atmosphere. Particulate phase Phenobarbital will be removed from the atmosphere by wet or dry deposition.

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If released to soil is expected to have high mobility based upon an estimated Koc of 59. Phenobarbital pKa is 7.3, indicating that this compound will exist partially in the anion form in the environment and anions generally do not adsorb more strongly to soils containing organic carbon than their neutral counterparts.

If released into water, Phenobarbital is not expected to adsorb to suspended solids and sediment based upon the estimated Koc. Phenobarbital, present at 100 mg/L, reached 0% of its theoretical BOD in 4 weeks.

**Bioaccumulation:** An estimated BCF of 4 suggests the potential for bioconcentration in aquatic organisms low. Phenobarbital is not expected to volatilize from dry soil surfaces.

**Leaching studies:** Phenobarbital is expected to have high mobility in soil.

**Other adverse effects:** Product not classified as environmentally hazardous. No major effects to aquatic organisms are expected, however; is recommended 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 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.

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**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 IV Controlled Substances (CIV).

**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 – Yes
Delayed Hazard – Yes
Fire Hazard – No
Pressure Hazard – No
Reactivity Hazard – No

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

**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).

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**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).

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

**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.

**Toxic Substances Control Act (TSCA)**:

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

| Ingredient | CAS No |
|---|---|
| Colloidal Silicon Dioxide, NF | 7631-86-9 |
| Magnesium Stearate, NF | 557-04-0 |
| Microcrystalline Cellulose, NF | 9004-34-6 |
| Sodium Starch Glycolate, NF | 9063-38-1 |

## SECTION 16 – OTHER INFORMATION

See current package insert for further information.

SDS prepared by Genus Lifesciences Inc.

Creation Date: Feb/24/25, New SDS

Revision Date: N/A

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

**Document Number:** WP-0842 **Revision:** 1
**Title:** SDS Phenobarbital Tablets (Human) - 64950
**Effective Date:** 26 Feb 2025

All dates and times are in Eastern Time.

## SDS Phenobarbital Tablets (Human) - 64950

### Department Approval

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| July Ortiz (JORTIZ) | | 26 Feb 2025, 11:34:52 AM | Approved |

### Regulatory Affairs Approval

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Demeitrius Sawickij (DSAWICKIJ) | | 26 Feb 2025, 03:06:05 PM | Approved |

### Quality Assurance Approval

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Rama Chitirala (RCHITIRALA) | Vice President of Quality Assurance | 26 Feb 2025, 03:11:10 PM | Approved |