



Safety Data Sheet

Section 1: Identification

Product identifier

- Product Name** • **AMYTAL® Sodium CII (Amobarbital Sodium for Injection, USP)**
- Product Code** • NDC 0187-4303-05; NDC 42998-303-01
- Product Description** • Prescription pharmaceutical product.

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

- Recommended use** • Sedative; hypnotic, for the short-term treatment of insomnia, since it appears to lose its effectiveness for sleep induction and sleep maintenance after 2 weeks; preanesthetic.
- Restrictions on use** • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

- Manufacturer** • Valeant Pharmaceuticals North America, LLC
400 Somerset Corporate Blvd.
Bridgewater, NJ 08807
United States
valeant.com
- Telephone (General)** • 1-800-321-4576

Emergency telephone number

- Manufacturer** • 1-800-535-5053 - US - Infotrac
- Manufacturer** • +1 352-323-3500 - International - Infotrac

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

- UN GHS** • Acute Toxicity Oral 3
Specific Target Organ Toxicity Single Exposure 3: Narcotic Effects
Carcinogenicity 2
Reproductive Toxicity 1

Label elements

UN GHS

DANGER



- Hazard statements** • Toxic if swallowed
 May cause drowsiness or dizziness
 Suspected of causing cancer.
 May damage fertility or the unborn child.

Precautionary statements

- Prevention** • Wash thoroughly after handling.
 Do not handle until all safety precautions have been read and understood.
 Avoid breathing dust, fume, gas, mist, vapours and/or spray.
 Use personal protective equipment as required.
- Response** • IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
- Storage/Disposal** • Store in a well-ventilated place. Keep container tightly closed.
 Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Other hazards

- UN GHS** • No data available

Section 3 - Composition/Information on Ingredients

Substances

Composition		
Chemical Name	Identifiers	%
Amobarbital sodium	CAS:64-43-7 EINECS:200-584-9	100%

Mixtures

- Material does not meet the criteria of a mixture.

Section 4: First-Aid Measures

Description of first aid measures

- Inhalation** • Normal use of this product does not pose an inhalation hazard. However, should respiratory tract irritation develop, discontinue use and remove to fresh air. Get medical attention if irritation or other symptoms develop or persist.
- Skin** • Wash skin with soap and water. If skin irritation occurs: Get medical advice/attention. Wash clothing separately before reuse.
- Eye** • IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
- Ingestion** • If swallowed, wash out mouth with water provided person is conscious. Seek medical attention.

Most important symptoms and effects, both acute and delayed

- Symptoms of oral overdose may occur within 15 minutes beginning with CNS depression, absent or sluggish reflexes, underventilation, hypotension, and hypothermia and may progress to pulmonary edema and death. Hemorrhagic blisters may develop, especially at pressure points.

Indication of any immediate medical attention and special treatment needed

- Notes to Physician** • Protect the patient's airway and support ventilation and perfusion. Meticulously

monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc. Absorption of drugs from the gastrointestinal tract may be decreased by giving activated charcoal, which, in many cases, is more effective than emesis or lavage; consider charcoal instead of or in addition to gastric emptying. Repeated doses of charcoal over time may hasten elimination of some drugs that have been absorbed. Safeguard the patient's airway when employing gastric emptying or charcoal.

Other information

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Additional details are available on the product package insert or the Physicians Desk Reference.

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media • SMALL FIRES: Dry chemical, CO2, water spray or regular foam.
LARGE FIRE: Water spray, fog or regular foam.

Unsuitable Extinguishing Media • No data available

Firefighting Procedures • As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards • None known - product is not flammable or combustible.

Hazardous Combustion Products • No data available

Advice for firefighters

- Structural firefighters' protective clothing provides limited protection in fire situations ONLY; it is not effective in spill situations where direct contact with the substance is possible.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions • Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Evacuate immediate area. Ventilate enclosed areas.

Emergency Procedures • Keep unauthorized personnel away. For bulk material spills: Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Ventilate closed spaces before entering.

Environmental precautions

- Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and material for containment and cleaning up

Containment/Clean-up Measures • Isolate hazard area. Prevent from entering drains and sewers. Cover with vermiculite or other suitable inert material, pick up and place in closed containers. Transport outdoors and hold for waste disposal. Ventilate area and wash spill site after material pickup is complete. Refer to Section 13 for appropriate disposal procedures.

Reference to other sections

- Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal

Considerations.

Section 7 - Handling and Storage

Precautions for safe handling

Handling

- Use only in well ventilated areas (preferably in a chemical fume hood). Do not breathe dusts, vapors or mists. Do not get in eyes, on skin, or on clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Use good safety and industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Storage

- Keep tightly closed. Store at room temperature 15-30°C (59-86°F), to maintain product integrity. use before expiration date marked on carton and/or container.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines

- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure controls

Engineering Measures/Controls

- Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment

Pictograms



Respiratory

- Where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with HEPA and organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

Eye/Face

- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging. Not required during normal clinical use.

Hands

- Wear protective gloves .

Skin/Body

- Wear protective gloves/protective clothing/eye protection/face protection. Not required during normal clinical use.

General Industrial Hygiene Considerations

- Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke during work. Avoid contact with skin, eyes or clothing. Wash thoroughly after handling.

Environmental Exposure Controls

- No special controls are required under conditions of intended use. In the event of a bulk spill, prevent spilled material from entering storm sewers or drains, waterways, and contact with the soil.

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Solid	Appearance/Description	white, friable, lyophilized granular powder.
Color	White	Odor	No odor.
General Properties			
Boiling Point	No data available	Melting Point/Freezing Point	No data available
Decomposition Temperature	No data available	pH	No data available
Specific Gravity/Relative Density	No data available	Water Solubility	Not relevant
Viscosity	Not relevant		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and humidities.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- This product is generally compatible with other common materials in a medical facility.

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Amobarbital sodium (100%)	64-43-7	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 505 mg/kg; Ingestion/Oral-Rat LD50 • 275 mg/kg

GHS Properties	Classification
Acute toxicity	UN GHS • Acute Toxicity - Oral 3
Skin corrosion/Irritation	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Classification criteria not met

Skin sensitization	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Carcinogenicity 2
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Toxic to Reproduction 1
STOT-SE	UN GHS • Specific Target Organ Toxicity Single Exposure 3: Narcotic Effects
STOT-RE	UN GHS • Classification criteria not met

Target Organs

- Central nervous system

Potential Health Effects

Inhalation

Acute (Immediate)

- Under normal conditions of use, no health effects are expected.

Chronic (Delayed)

- No data available

Skin

Acute (Immediate)

- Non-irritating to skin or mucous membranes when used as directed.

Chronic (Delayed)

- No data available

Eye

Acute (Immediate)

- May cause mild eye irritation with direct contact to eye.

Chronic (Delayed)

- No data available

Ingestion

Acute (Immediate)

- Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested.

Chronic (Delayed)

- No data available

Carcinogenic Effects

- Animal Data. Phenobarbital sodium is carcinogenic in mice and rats after lifetime administration. In mice, it produced benign and malignant liver cell tumors. In rats, benign liver cell tumors were observed very late in life. Human Data — In a 29-year epidemiologic study of 9,136 patients who were treated on an anticonvulsant protocol that included phenobarbital, results indicated a higher than normal incidence of hepatic carcinoma. Previously, some of these patients had been treated with thorostrast, a drug that is known to produce hepatic carcinomas. Thus, this study did not provide sufficient evidence that phenobarbital sodium is carcinogenic in humans. A retrospective study of 84 children with brain tumors matched to 73 normal controls and 78 cancer controls (malignant disease other than brain tumors) suggested an association between exposure to barbiturates prenatally and an increased incidence of brain tumors.

Reproductive Effects

- Barbiturates can cause fetal damage when administered to a pregnant woman. Retrospective, case-controlled studies have suggested a connection between the maternal consumption of barbiturates and a higher than expected incidence of fetal abnormalities. Barbiturates readily cross the placental barrier and are distributed throughout fetal tissues; the highest concentrations are found in the placenta, fetal liver, and brain. Fetal blood levels approach maternal blood levels following parenteral administration. Withdrawal symptoms occur in infants born to women who receive barbiturates throughout the last trimester of pregnancy.

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IMO/IMDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IATA/ICAO	Not Applicable	Not Regulated	Not Applicable	Not Applicable	

Special precautions for user

- No data available

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

- No data available

Section 15 - Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA Hazard Classifications

- No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Amobarbital sodium	64-43-7	Yes	Yes	No

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

- Amobarbital sodium 64-43-7 Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

- Amobarbital sodium 64-43-7 Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

- Amobarbital sodium 64-43-7 Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Amobarbital sodium

64-43-7

Not Listed

Section 16 - Other Information

Revision Date

- 08/January/2016

Last Revision Date

- 08/January/2016

Preparation Date

- 08/January/2016

Disclaimer/Statement of Liability

- The above information and recommendations contained in the Safety Data Sheet have been compiled from sources believed to be accurate and reliable and to represent the most reasonable current opinion on the subject as of the date the SDS was prepared. No warranty, guaranty, or representation is made as to the correctness or sufficiency of the information. Such data are offered solely for consideration, investigation, and verification but do not purport to be all inclusive and should be used only as a guide. The user of this product must decide what safety measures are necessary to safely use this product, either alone or in combination with other products, and determine its environmental regulatory compliance obligations under any applicable federal or state laws.