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

<table>
<thead>
<tr>
<th>Substances</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Name</td>
<td>Identifiers</td>
</tr>
<tr>
<td>Amobarbital sodium</td>
<td>CAS: 64-43-7</td>
</tr>
<tr>
<td>EINECS: 200-584-9</td>
<td></td>
</tr>
</tbody>
</table>

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 15-30ºC (59-86ºF), 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

<table>
<thead>
<tr>
<th>Physical Form</th>
<th>Solid</th>
<th>Appearance/Description</th>
<th>white, friable, lyophilized granular powder.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>White</td>
<td>Odor</td>
<td>No odor.</td>
</tr>
</tbody>
</table>

General Properties

| Boiling Point          | No data available |
| Decomposition Temperature | No data available |
| Melting Point/Freezing Point | No data available |
| Specific Gravity/Relative Density | No data available |
| Water Solubility       | Not relevant     |
| Viscosity             | Not relevant     |

Vapour Pressure

| Vapor Pressure | Not relevant |
| Evaporation Rate | Not relevant |

Flammability

| Flash Point          | Not relevant |
| LEL                 | Not relevant |
| Autoignition        | 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

<table>
<thead>
<tr>
<th>Components</th>
<th>Acute Toxicity: Ingestion/Oral-Mouse LD50 • 505 mg/kg; Ingestion/Oral-Rat LD50 • 275 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amobarbital sodium (100%)</td>
<td>64-43-7</td>
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</tbody>
</table>

GHS Properties

<table>
<thead>
<tr>
<th>Classifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
</tr>
<tr>
<td>Skin corrosion/Irritation</td>
</tr>
<tr>
<td>Serious eye damage/Irritation</td>
</tr>
<tr>
<td>Skin Sensitization</td>
</tr>
<tr>
<td>------------------------------------</td>
</tr>
<tr>
<td>Respiratory Sensitization</td>
</tr>
<tr>
<td>Aspiration Hazard</td>
</tr>
<tr>
<td>Carcinogenicity</td>
</tr>
<tr>
<td>Germ Cell Mutagenicity</td>
</tr>
<tr>
<td>Toxicity for Reproduction</td>
</tr>
<tr>
<td>STOT-SE</td>
</tr>
<tr>
<td>STOT-RE</td>
</tr>
</tbody>
</table>

**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 thorotrast, 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

<table>
<thead>
<tr>
<th>~</th>
<th>UN number</th>
<th>UN proper shipping name</th>
<th>Transport hazard class(es)</th>
<th>Packing group</th>
<th>Environmental hazards</th>
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</thead>
<tbody>
<tr>
<td>DOT</td>
<td>Not Applicable</td>
<td>Not Regulated</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>IMO/IMDG</td>
<td>Not Applicable</td>
<td>Not Regulated</td>
<td>Not Applicable</td>
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<tr>
<td>IATA/ICAO</td>
<td>Not Applicable</td>
<td>Not Regulated</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS</th>
<th>Canada DSL</th>
<th>EU EINECS</th>
<th>TSCA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amobarbital sodium</td>
<td>64-43-7</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

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 |
<table>
<thead>
<tr>
<th>Listing</th>
<th>Section 16 - Other Information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Revision Date</strong></td>
</tr>
<tr>
<td></td>
<td>08/January/2016</td>
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<td></td>
<td><strong>Preparation Date</strong></td>
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<td></td>
<td><strong>Disclaimer/Statement of Liability</strong></td>
</tr>
</tbody>
</table>
|         | 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.