SAFETY DATA SHEET

Pentobarbital Sodium / Phenytoin Formulation

SECTION 1. IDENTIFICATION

Product name : Pentobarbital Sodium / Phenytoin Formulation

Manufacturer or supplier's details
Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
           Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Flammable liquids : Category 3
Acute toxicity (Oral) : Category 3
Skin sensitization : Category 1
Carcinogenicity (Oral) : Category 2
Reproductive toxicity : Category 2
Specific target organ toxicity - single exposure : Category 1 (Central nervous system)
Specific target organ toxicity - repeated exposure : Category 1 (Central nervous system)

GHS label elements
Hazard pictograms : 
Signal Word : Danger
Hazard Statements : H226 Flammable liquid and vapor.
H301 Toxic if swallowed.
H317 May cause an allergic skin reaction.
H351 Suspected of causing cancer if swallowed.
H361 Suspected of damaging fertility or the unborn child.
H370 Causes damage to organs (Central nervous system).
H372 Causes damage to organs (Central nervous system)
through prolonged or repeated exposure.

Precautionary Statements:

**Prevention:**
- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P210 Keep away from heat, sparks, open flame and hot surfaces. No smoking.
- P233 Keep container tightly closed.
- P241 Use explosion-proof electrical, ventilating and lighting equipment.
- P242 Use only non-sparking tools.
- P243 Take precautionary measures against static discharge.
- P260 Do not breathe mist or vapors.
- P264 Wash skin thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P272 Contaminated work clothing must not be allowed out of the workplace.
- P280 Wear protective gloves, protective clothing, eye protection and face protection.

**Response:**
- P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER. Rinse mouth.
- P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
- P307 + P311 IF exposed: Call a doctor.
- P333 + P313 If skin irritation or rash occurs: Get medical attention.
- P363 Wash contaminated clothing before reuse.

**Storage:**
- P403 + P235 Store in a well-ventilated place. Keep cool.
- P405 Store locked up.

**Disposal:**
- P501 Dispose of contents and container to an approved waste disposal plant.

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Other hazards
Vapors may form explosive mixture with air.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Components</strong></td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Pentobarbital sodium</td>
<td>57-33-0</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
</tr>
<tr>
<td>Ethanol#</td>
<td>64-17-5</td>
</tr>
<tr>
<td>Phenytoin sodium</td>
<td>630-93-3</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
</tr>
<tr>
<td># Voluntarily-disclosed substance</td>
<td></td>
</tr>
</tbody>
</table>
SECTION 4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air. Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Call a physician or poison control center immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed: Toxic if swallowed. May cause an allergic skin reaction. Suspected of causing cancer if swallowed. Suspected of damaging fertility or the unborn child. Causes damage to organs. Causes damage to organs through prolonged or repeated exposure.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
 Alcohol-resistant foam
 Carbon dioxide (CO2)
 Dry chemical

Unsuitable extinguishing media: High volume water jet

Specific hazards during fire fighting: Do not use a solid water stream as it may scatter and spread fire. Flash back possible over considerable distance. Vapors may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
 Nitrogen oxides (NOx)
 Metal oxides

Specific extinguishing method: Use extinguishing measures that are appropriate to local cir-
odds cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

Special protective equipment for fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Remove all sources of ignition. Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Non-sparking tools should be used. Soak up with inert absorbent material. Suppress (knock down) gases/vapors/mists with a water spray jet. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation. Use explosion-proof electrical, ventilating and lighting equipment.

Advice on safe handling: Do not get on skin or clothing. Do not breathe mist or vapors. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety
practice, based on the results of the workplace exposure assessment.
Non-sparking tools should be used.
Keep container tightly closed.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage: Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Keep in a cool, well-ventilated place.
Store in accordance with the particular national regulations.
Keep away from heat and sources of ignition.

Materials to avoid: Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Flammable solids
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures which in contact with water emit flammable gases
Explosives
Gases
Very acutely toxic substances and mixtures

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentobarbital sodium</td>
<td>57-33-0</td>
<td>TWA</td>
<td>40µg/m³ (OEB3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>400µg/100cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>US WEEL</td>
</tr>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>STEL</td>
<td>1,000 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>1,000 ppm 1,900 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>1,000 ppm 1,900 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td>Phenytoin sodium</td>
<td>630-93-3</td>
<td>TWA</td>
<td>50 µg/m³ (OEB3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>500 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>TWA</td>
<td>10 ppm</td>
<td>US WEEL</td>
</tr>
</tbody>
</table>

Engineering measures: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections).
All engineering controls should be implemented by facility
design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Use explosion-proof electrical, ventilating and lighting equipment.

### Personal protective equipment

**Respiratory protection**

General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**Hand protection**

**Material**

Chemical-resistant gloves

**Remarks**

Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.

**Eye protection**

Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection**

Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

**Hygiene measures**

If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Color</td>
<td>pink</td>
</tr>
<tr>
<td>Odor</td>
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</tr>
<tr>
<td>Odor Threshold</td>
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</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
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</tr>
<tr>
<td>Flash point</td>
<td>111 - 140 °F / 44 - 60 °C</td>
</tr>
<tr>
<td>Evaporation rate</td>
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</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
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</tr>
<tr>
<td>Relative vapor density</td>
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</tr>
<tr>
<td>Relative density</td>
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</tr>
<tr>
<td>Density</td>
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<tr>
<td>Solubility(ies)</td>
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</tr>
<tr>
<td>Water solubility</td>
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</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
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</tr>
<tr>
<td>Autoignition temperature</td>
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<tr>
<td>Decomposition temperature</td>
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</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
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</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
</tbody>
</table>
Oxidizing properties: The substance or mixture is not classified as oxidizing.

Molecular weight: No data available

Particle size: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reac-tions:
- Flammable liquid and vapor.
- Vapors may form explosive mixture with air.
- Can react with strong oxidizing agents.

Conditions to avoid: Heat, flames and sparks.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity:
Toxic if swallowed.

Product:

Acute oral toxicity:
- Acute toxicity estimate: 261.96 mg/kg
  Method: Calculation method

Acute inhalation toxicity:
- Acute toxicity estimate: > 200 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: Calculation method

Components:

Pentobarbital sodium:
- Acute oral toxicity:
  - LD50 (Rat): 118 mg/kg
  - LD50 (Mouse): 239 mg/kg
  - LD50 (Rabbit): 175 mg/kg
  - LD50 (Dog): 65 mg/kg

Propylene glycol:
- Acute oral toxicity:
  - LD50 (Rat): 22,000 mg/kg
## Acute inhalation toxicity
- **LC50 (Rat):** > 44.9 mg/l
- **Exposure time:** 4 h
- **Test atmosphere:** dust/mist

## Acute dermal toxicity
- **LD50 (Rabbit):** > 2,000 mg/kg
- **Assessment:** The substance or mixture has no acute dermal toxicity

### Ethanol:
- **Acute oral toxicity:**
  - **LD50 (Rat):** > 5,000 mg/kg
  - **Method:** OECD Test Guideline 401

- **Acute inhalation toxicity:**
  - **LC50 (Rat):** 124.7 mg/l
  - **Exposure time:** 4 h
  - **Test atmosphere:** vapor

### Phenytoin sodium:
- **Acute oral toxicity:**
  - **Acute toxicity estimate:** 100 mg/kg
  - **Method:** Expert judgment

### Benzyl alcohol:
- **Acute oral toxicity:**
  - **LD50 (Rat):** 1,620 mg/kg

- **Acute inhalation toxicity:**
  - **LC50 (Rat):** > 4,178 mg/l
  - **Exposure time:** 4 h
  - **Test atmosphere:** dust/mist
  - **Method:** OECD Test Guideline 403

## Skin corrosion/irritation
Not classified based on available information.

### Components:

#### Propylene glycol:
- **Species:** Rabbit
- **Method:** OECD Test Guideline 404
- **Result:** No skin irritation

#### Ethanol:
- **Species:** Rabbit
- **Method:** OECD Test Guideline 404
- **Result:** No skin irritation

#### Benzyl alcohol:
- **Species:** Rabbit
- **Method:** OECD Test Guideline 404
- **Result:** No skin irritation

## Serious eye damage/eye irritation
Not classified based on available information.
Components:

Propylene glycol:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

Ethanol:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405

Benzyl alcohol:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405

Respiratory or skin sensitization

Skin sensitization
May cause an allergic skin reaction.

Respiratory sensitization
Not classified based on available information.

Components:

Propylene glycol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative

Ethanol:
Test Type: Local lymph node assay (LLNA)
Routes of exposure: Skin contact
Species: Mouse
Result: negative

Phenytoin sodium:
Assessment: Probability or evidence of skin sensitization in humans

Benzyl alcohol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Germ cell mutagenicity
Not classified based on available information.
Components:

**Propylene glycol:**
- **Genotoxicity in vitro:**
  - Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
  - Test Type: Chromosome aberration test in vitro
    - Method: OECD Test Guideline 473
    - Result: negative

- **Genotoxicity in vivo:**
  - Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
    - Species: Mouse
    - Application Route: Intraperitoneal injection
    - Result: negative

**Ethanol:**
- **Genotoxicity in vitro:**
  - Test Type: In vitro mammalian cell gene mutation test
    - Result: negative
  - Test Type: Bacterial reverse mutation assay (AMES)
    - Result: negative

- **Genotoxicity in vivo:**
  - Test Type: Rodent dominant lethal test (germ cell) (in vivo)
    - Species: Mouse
    - Application Route: Ingestion
    - Result: equivocal

**Phenytoin sodium:**
- **Genotoxicity in vitro:**
  - Test Type: Bacterial reverse mutation assay (AMES)
    - Result: negative
    - Remarks: Based on data from similar materials
  - Test Type: Chromosome aberration test in vitro
    - Result: negative
    - Remarks: Based on data from similar materials
  - Test Type: In vitro sister chromatid exchange assay in mammalian cells
    - Result: positive
    - Remarks: Based on data from similar materials

- **Genotoxicity in vivo:**
  - Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
    - Species: Mouse
    - Application Route: Ingestion
    - Result: negative
    - Remarks: Based on data from similar materials

**Benzyl alcohol:**
- **Genotoxicity in vitro:**
  - Test Type: Bacterial reverse mutation assay (AMES)
    - Result: negative
## Genotoxicity in vivo
- **Test Type:** Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
- **Species:** Mouse
- **Application Route:** Intraperitoneal injection
- **Result:** negative

## Carcinogenicity
Suspected of causing cancer if swallowed.

### Components:

#### Propylene glycol:
- **Species:** Rat
- **Application Route:** Ingestion
- **Exposure time:** 2 Years
- **Result:** negative

#### Phenytoin sodium:
- **Species:** Rat
- **Application Route:** Ingestion
- **Exposure time:** 2 Years
- **Result:** negative

- **Species:** Mouse
  - **Application Route:** Ingestion
  - **Exposure time:** 2 Years
  - **Result:** positive

  **Carcinogenicity - Assessment:** Limited evidence of carcinogenicity in animal studies (oral)

#### Benzyl alcohol:
- **Species:** Mouse
  - **Application Route:** Ingestion
  - **Exposure time:** 103 weeks
  - **Method:** OECD Test Guideline 451
  - **Result:** negative

### IARC
- **Group 2B:** Possibly carcinogenic to humans
  - Phenytoin sodium
  - 630-93-3

### OSHA
- No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

### NTP
- Reasonably anticipated to be a human carcinogen
  - Phenytoin sodium
  - 630-93-3

### Reproductive toxicity
Suspected of damaging fertility or the unborn child.

### Components:

#### Pentobarbital sodium:
- **Reproductive toxicity - Assessment:** Some evidence of adverse effects on development, based on...
**SAFETY DATA SHEET**

**Pentobarbital Sodium / Phenytoin Formulation**

**Version** 7.5  **Revision Date:** 04/04/2023  **SDS Number:** 671678-00020  **Date of last issue:** 10/01/2022  **Date of first issue:** 05/12/2016

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**Propylene glycol:**

**Effects on fertility**
- Test Type: Two-generation reproduction toxicity study
- Species: Mouse
- Application Route: Ingestion
- Result: negative

**Effects on fetal development**
- Test Type: Embryo-fetal development
- Species: Mouse
- Application Route: Ingestion
- Result: negative

**Ethanol:**

**Effects on fertility**
- Test Type: Two-generation reproduction toxicity study
- Species: Mouse
- Application Route: Ingestion
- Result: negative

**Phenytoin sodium:**

**Effects on fertility**
- Test Type: Reproductive and developmental toxicity study
- Species: Rat
- Application Route: Ingestion
- Result: positive
- Remarks: Based on data from similar materials

**Effects on fetal development**
- Test Type: Reproductive and developmental toxicity study
- Species: Rat
- Application Route: Ingestion
- Result: positive
- Remarks: Based on data from similar materials

**Reproductive toxicity - Assessment**
- Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.

**Benzyl alcohol:**

**Effects on fertility**
- Test Type: Fertility/early embryonic development
- Species: Rat
- Application Route: Ingestion
- Result: negative
- Remarks: Based on data from similar materials

**Effects on fetal development**
- Test Type: Embryo-fetal development
- Species: Mouse
- Application Route: Ingestion
- Result: negative

**STOT-single exposure**
- Causes damage to organs (Central nervous system).
Components:
Pentobarbital sodium:
Routes of exposure: Ingestion
Target Organs: Central nervous system
Assessment: Causes damage to organs.

STOT-repeated exposure
Causes damage to organs (Central nervous system) through prolonged or repeated exposure.

Components:
Phenytoin sodium:
Routes of exposure: Ingestion
Target Organs: Central nervous system
Assessment: Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

Repeated dose toxicity
Components:
Propylene glycol:
Species: Rat, male
NOAEL: >= 1,700 mg/kg
Application Route: Ingestion
Exposure time: 2 y

Ethanol:
Species: Rat
NOAEL: 1,280 mg/kg
LOAEL: 3,156 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

Phenytoin sodium:
Species: Rat
NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 13 Weeks
Remarks: Based on data from similar materials

Species: Mouse
NOAEL: > 10 - 100 mg/kg
LOAEL: > 10 - 100 mg/kg
Application Route: Ingestion
Exposure time: 13 Weeks
Remarks: Based on data from similar materials

Benzyl alcohol:
Species: Rat
NOAEL: 1.072 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 28 Days
Method: OECD Test Guideline 412

**Aspiration toxicity**
Not classified based on available information.

**Experience with human exposure**

**Components:**

**Pentobarbital sodium:**
Ingestion: Symptoms: dry mouth, mood swings, Dizziness, Headache, Nausea, central nervous system effects, Sweating

**Phenytoin sodium:**
Ingestion: Symptoms: Nausea, constipation, confusion, Vomiting, central nervous system effects, Dizziness, insomnia, Blood disorders, Liver disorders, Tremors, anorexia

**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Pentobarbital sodium:**
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 49.5 mg/l Exposure time: 96 h

**Propylene glycol:**
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l Exposure time: 48 h

Toxicity to algae/aquatic plants: ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
Toxicity to microorganisms: NOEC (Pseudomonas putida): > 20,000 mg/l Exposure time: 18 h

**Ethanol:**
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceriodaphnia (water flea)): > 1,000 mg/l Exposure time: 48 h
### Toxicity to algae/aquatic plants

**ErC50 (Chlorella vulgaris (Fresh water algae))**: 275 mg/l
- Exposure time: 72 h

**EC10 (Chlorella vulgaris (Fresh water algae))**: 11.5 mg/l
- Exposure time: 72 h

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

**NOEC (Daphnia magna (Water flea))**: 9.6 mg/l
- Exposure time: 9 d

### Toxicity to microorganisms

**EC50 (Pseudomonas putida)**: 6,500 mg/l
- Exposure time: 16 h

### Phenytoin sodium:

**Toxicity to fish**

**EC50 (Danio rerio (zebra fish))**: > 10 - 100 mg/l
- Exposure time: 72 h
- Remarks: Based on data from similar materials

### Benzyl alcohol:

**Toxicity to fish**

**LC50 (Pimephales promelas (fathead minnow))**: 460 mg/l
- Exposure time: 96 h

**Toxicity to daphnia and other aquatic invertebrates**

**EC50 (Daphnia magna (Water flea))**: 230 mg/l
- Exposure time: 48 h
- Method: OECD Test Guideline 202

**Toxicity to algae/aquatic plants**

**EC50 (Pseudokirchneriella subcapitata (green algae))**: 770 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

**NOEC (Pseudokirchneriella subcapitata (green algae))**: 310 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**

**NOEC (Daphnia magna (Water flea))**: 51 mg/l
- Exposure time: 21 d
- Method: OECD Test Guideline 211

### Persistence and degradability

**Components:**

**Propylene glycol:**

- **Biodegradability**: Readily biodegradable.
- **Biodegradation**: 98.3 %
- **Exposure time**: 28 d
- **Method**: OECD Test Guideline 301F

**Ethanol:**
Biodegradability : Result: Readily biodegradable.
Biodegradation: 84 %
Exposure time: 20 d

Phenytoin sodium:
Biodegradability : Result: Not readily biodegradable.
Method: OECD Test Guideline 301C
Remarks: Based on data from similar materials

Benzyl alcohol:
Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

Bioaccumulative potential

Components:

Propylene glycol:
Partition coefficient: n-octanol/water
: log Pow: -1.07

Ethanol:
Partition coefficient: n-octanol/water
: log Pow: -0.35

Phenytoin sodium:
Partition coefficient: n-octanol/water
: log Pow: 2.84
Remarks: Calculation

Benzyl alcohol:
Partition coefficient: n-octanol/water
: log Pow: 1.05

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
Empty containers retain residue and can be dangerous.
Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death.
SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 1993
Proper shipping name : FLAMMABLE LIQUID, N.O.S.
/Ethanol, Pentobarbital sodium/
Class : 3
Packing group : III
Labels : 3

IATA-DGR
UN/ID No. : UN 1993
Proper shipping name : Flammable liquid, n.o.s.
/Ethanol, Pentobarbital sodium/
Class : 3
Packing group : III
Labels : Flammable Liquids
Packing instruction (cargo aircraft) : 366
Packing instruction (passenger aircraft) : 355

IMDG-Code
UN number : UN 1993
Proper shipping name : FLAMMABLE LIQUID, N.O.S.
/Ethanol, Pentobarbital sodium/
Class : 3
Packing group : III
Labels : 3
EmS Code : F-E, S-E
Marine pollutant : no

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

49 CFR
UN/ID/NA number : NA 1993
Proper shipping name : Combustible liquid, n.o.s.
/Ethanol, Pentobarbital sodium/
Class : CBL
Packing group : III
Labels : NONE
ERG Code : 128
Marine pollutant : no
Remarks : Above applies only to containers over 119 gallons or 450 liters. Not regulated if shipped in packages less than or equal to 119 gallons (450 liters). If transporting by vessel or aircraft, unless other means of transportation is impracticable, then the product must be shipped as a flammable liquid.
SAFETY DATA SHEET
Pentobarbital Sodium / Phenytoin Formulation

Version 7.5  Revision Date: 04/04/2023  SDS Number: 671678-00020  Date of last issue: 10/01/2022  Date of first issue: 05/12/2016

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards: Flammable (gases, aerosols, liquids, or solids)  Acute toxicity (any route of exposure)  Respiratory or skin sensitization  Carcinogenicity  Reproductive toxicity  Specific target organ toxicity (single or repeated exposure)

SARA 313: The following components are subject to reporting levels established by SARA Title III, Section 313:

<table>
<thead>
<tr>
<th>Component</th>
<th>Reporting Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentobarbital sodium</td>
<td>57-33-0  &gt;= 30 - &lt; 50 %</td>
</tr>
</tbody>
</table>

US State Regulations

Pennsylvania Right To Know

<table>
<thead>
<tr>
<th>Component</th>
<th>Reporting Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentobarbital sodium</td>
<td>57-33-0</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
</tr>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
</tr>
<tr>
<td>Phenytoin sodium</td>
<td>630-93-3</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
</tr>
</tbody>
</table>

California Prop. 65
WARNING: This product can expose you to chemicals including Phenytoin sodium, which is/are known to the State of California to cause cancer, and Pentobarbital sodium, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances

<table>
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<th>Reporting Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
</tr>
<tr>
<td>Phenytoin sodium</td>
<td>630-93-3</td>
</tr>
</tbody>
</table>

California Permissible Exposure Limits for Chemical Contaminants

<table>
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<tr>
<th>Component</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
</tr>
</tbody>
</table>

The ingredients of this product are reported in the following inventories:

AICS: not determined
SECTION 16. OTHER INFORMATION

Further information

**NFPA 704:**

Flammability

Instability

Health

HMIS® IV:

**HEALTH**
- *
- 4

**FLAMMABILITY**
- 2

**PHYSICAL HAZARD**
- 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / STEL : USA. Workplace Environmental Exposure Levels (WEEL)
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA : 8-hour time weighted average
US WEEL / TWA : 8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; BC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organiza-
### SAFETY DATA SHEET

**Pentobarbital Sodium / Phenytoin Formulation**

<table>
<thead>
<tr>
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<th>Date of last issue</th>
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<td>04/04/2023</td>
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<td>10/01/2022</td>
<td>05/12/2016</td>
</tr>
</tbody>
</table>

**Revision Date:** 04/04/2023

**SDS Number:** 671678-00020

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

**US / Z8**