

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.7	09/28/2024	671678-00022	Date of first issue: 05/12/2016

### 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 : EHSDATASTEWARD@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 : Category 1 (Central nervous system)  
- single exposure  
Specific target organ toxicity : Category 1 (Central nervous system)  
- repeated exposure

#### 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)

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version 7.7      Revision Date: 09/28/2024      SDS Number: 671678-00022      Date of last issue: 09/30/2023  
Date of first issue: 05/12/2016

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.

### Other hazards

Vapors may form explosive mixture with air.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Pentobarbital sodium	57-33-0	$\geq 30 - < 50$
Propylene glycol	57-55-6	$\geq 10 - < 20$
Ethanol#	64-17-5	$\geq 10 - < 20$
Phenytoin sodium	630-93-3	$\geq 5 - < 10$
Benzyl alcohol	100-51-6	$\geq 1 - < 5$

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.7	09/28/2024	671678-00022	Date of first issue: 05/12/2016

# Voluntarily-disclosed substance  
Actual concentration is withheld as a trade secret

### 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 (CO <sub>2</sub> ) 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 (NO <sub>x</sub> )

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.7	09/28/2024	671678-00022	Date of first issue: 05/12/2016

Metal oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances 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 equip-

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version 7.7      Revision Date: 09/28/2024      SDS Number: 671678-00022      Date of last issue: 09/30/2023  
Date of first issue: 05/12/2016

- Advice on safe handling : ment.  
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

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version 7.7      Revision Date: 09/28/2024      SDS Number: 671678-00022      Date of last issue: 09/30/2023  
Date of first issue: 05/12/2016

		Wipe limit	500 µg/100 cm <sup>2</sup>	Internal
Benzyl alcohol	100-51-6	TWA	10 ppm	US WEEL

**Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less 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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.7	09/28/2024	671678-00022	Date of first issue: 05/12/2016

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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: liquid
Color	: pink
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: 111 - 140 °F / 44 - 60 °C
Evaporation rate	: No data available
Flammability (solid, gas)	: Not applicable
Flammability (liquids)	: Not applicable
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapor pressure	: No data available
Relative vapor density	: No data available
Relative density	: No data available
Density	: No data available
Solubility(ies) Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.7	09/28/2024	671678-00022	Date of first issue: 05/12/2016

Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics	:	
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 reactions	:	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: 261.66 mg/kg Method: Calculation method
---------------------	---	---

#### Components:

##### Pentobarbital sodium:

Acute oral toxicity	:	LD50 (Rat): 118 mg/kg LD50 (Mouse): 239 mg/kg
---------------------	---	--



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.7	09/28/2024	671678-00022	Date of first issue: 05/12/2016

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): 10,470 mg/kg  
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat, male): 116.9 mg/l  
Exposure time: 4 h  
Test atmosphere: vapor

Acute dermal toxicity : LD50 (Rabbit): > 15,800 mg/kg

### Phenytoin sodium:

Acute oral toxicity : Acute toxicity estimate: 100 mg/kg  
Method: Expert judgment

### Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.4 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: The substance or mixture has no acute inhalation toxicity

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Propylene glycol:

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation

#### Ethanol:

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.7	09/28/2024	671678-00022	Date of first issue: 05/12/2016

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	:	Mouse ear swelling test (MEST)
Routes of exposure	:	Skin contact
Species	:	Mouse
Result	:	negative

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.7	09/28/2024	671678-00022	Date of first issue: 05/12/2016

---

### Phenytoin sodium:

Assessment : Probability or evidence of skin sensitization in humans

### Benzyl alcohol:

Test Type : Human repeat insult patch test (HRIPT)  
Routes of exposure : Skin contact  
Species : Humans  
Result : positive

Assessment : Probability or evidence of low to moderate skin sensitization rate in humans

### 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: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Rat  
Application Route: Ingestion  
Result: negative

### Phenytoin sodium:

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.7	09/28/2024	671678-00022	Date of first issue: 05/12/2016

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.7	09/28/2024	671678-00022	Date of first issue: 05/12/2016

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

<b>IARC</b>	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.

<b>NTP</b>	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 animal experiments.

#### **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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.7	09/28/2024	671678-00022	Date of first issue: 05/12/2016

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 :  $\geq 1,700$  mg/kg  
Application Route : Ingestion  
Exposure time : 2 y

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.7	09/28/2024	671678-00022	Date of first issue: 05/12/2016

### Ethanol:

Species	: Rat
NOAEL	: 1,730 mg/kg
LOAEL	: 3,200 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:

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.7	09/28/2024	671678-00022	Date of first issue: 05/12/2016

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

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

Toxicity to daphnia and other : NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l  
aquatic invertebrates (Chronic toxicity) Exposure time: 7 d

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 20,000 mg/l  
Exposure time: 18 h

### Ethanol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 14,200 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Ceriodaphnia dubia (water flea)): 5,012 mg/l  
aquatic invertebrates Exposure time: 48 h

Toxicity to algae/aquatic : ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l  
plants Exposure time: 72 h

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

Toxicity to fish (Chronic toxicity) : NOEC (Oryzias latipes (Japanese medaka)): >= 79 mg/l  
Exposure time: 100 d

Toxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): 9.6 mg/l  
aquatic invertebrates (Chronic toxicity) Exposure time: 9 d

Toxicity to microorganisms : EC50 (Protozoa): 5,800 mg/l  
Exposure time: 4 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

Toxicity to daphnia and other : Remarks: No toxicity at the limit of solubility.  
aquatic invertebrates

### Benzyl alcohol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.7	09/28/2024	671678-00022	Date of first issue: 05/12/2016

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 : Result: 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- : log Pow: -1.07

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.7	09/28/2024	671678-00022	Date of first issue: 05/12/2016

octanol/water

Method: Regulation (EC) No. 440/2008, Annex, A.8

### 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.  
If not otherwise specified: Dispose of as unused product.

## 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  
Environmentally hazardous : no

#### IATA-DGR

UN/ID No. : UN 1993  
Proper shipping name : Flammable liquid, n.o.s.  
(Ethanol, Pentobarbital sodium)  
Class : 3  
Packing group : III

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.7	09/28/2024	671678-00022	Date of first issue: 05/12/2016

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.

### 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.7	09/28/2024	671678-00022	Date of first issue: 05/12/2016

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:

Pentobarbital sodium	57-33-0	>= 30 - < 50 %
----------------------	---------	----------------

### US State Regulations

#### Pennsylvania Right To Know

Pentobarbital sodium	57-33-0
Water	7732-18-5
Propylene glycol	57-55-6
Ethanol	64-17-5
Phenytoin sodium	630-93-3
Benzyl alcohol	100-51-6

#### 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](http://www.P65Warnings.ca.gov).

#### California List of Hazardous Substances

Ethanol	64-17-5
Phenytoin sodium	630-93-3

#### California Permissible Exposure Limits for Chemical Contaminants

Ethanol	64-17-5
---------	---------

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

AICS : not determined

DSL : not determined

IECSC : not determined

## SECTION 16. OTHER INFORMATION

### Further information

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

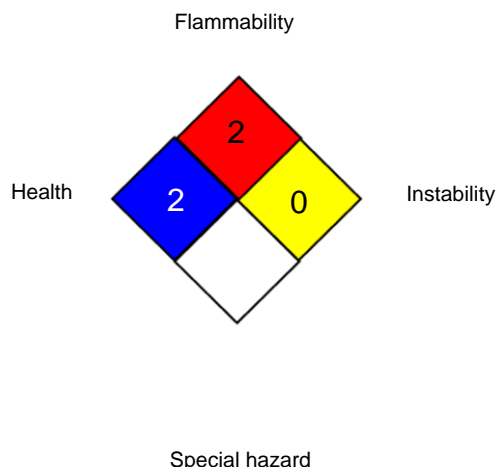
Version  
7.7

Revision Date:  
09/28/2024

SDS Number:  
671678-00022

Date of last issue: 09/30/2023  
Date of first issue: 05/12/2016

### NFPA 704:



### 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	:	Short-term exposure limit
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; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pentobarbital Sodium / Phenytoin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
7.7	09/28/2024	671678-00022	Date of first issue: 05/12/2016

---

Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 09/28/2024

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