

**Pentobarbital Sodium / Phenytoin Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 05/24/2017  |
| 4.0     | 10/09/2017     | 671678-00006 | 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 : 2000 Galloping Hill Road  
Kenilworth - New Jersey - USA 1685

Telephone : 908-740-4000

Telefax : 908-735-1496

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

**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with 29 CFR 1910.1200**

Flammable liquids : Category 3

Acute toxicity (Oral) : Category 3

Carcinogenicity : Category 2

Reproductive toxicity : Category 2

Specific target organ  
systemic toxicity - single  
exposure : Category 1 (Central nervous system)

Specific target organ  
systemic 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.  
H351 Suspected of causing cancer.

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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 flames/hot surfaces. No smoking.  
P233 Keep container tightly closed.  
P241 Use explosion-proof electrical/ ventilating/ 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.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER/doctor. Rinse mouth.  
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.  
P307 + P311 IF exposed: Call a POISON CENTER or doctor/physician.

**Storage:**

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

**Disposal:**

P501 Dispose of contents/ 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

**Hazardous ingredients**

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

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**SECTION 4. FIRST AID MEASURES**

- |                                                             |                                                                                                                                                                                                                |
|-------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| General advice                                              | : In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice.                                                       |
| If inhaled                                                  | : If inhaled, remove to fresh air.<br>Get medical attention.                                                                                                                                                   |
| In case of skin contact                                     | : In case of contact, immediately flush skin with plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact                                      | : Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists.                                                                                                         |
| If swallowed                                                | : If swallowed, DO NOT induce vomiting.<br>Call a physician or poison control center immediately.<br>Rinse mouth thoroughly with water.<br>Never give anything by mouth to an unconscious person.              |
| Most important symptoms and effects, both acute and delayed | : Toxic if swallowed.<br>Suspected of causing cancer.<br>Suspected of damaging fertility or the unborn child.<br>Causes damage to organs.<br>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.                                                  |
| Notes to physician                                          | : Treat symptomatically and supportively.                                                                                                                                                                      |

**SECTION 5. FIRE-FIGHTING MEASURES**

- |                                       |                                                                                                                                                                                                                                       |
|---------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Suitable extinguishing media          | : Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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.<br>Flash back possible over considerable distance.<br>Vapors may form explosive mixtures with air.<br>Exposure to combustion products may be a hazard to health. |
| Hazardous combustion prod-            | : Carbon oxides                                                                                                                                                                                                                       |

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|             |                                                |                                                                                                                                                                                                                                                   |
|-------------|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <div></div> |                                                | Nitrogen oxides (NO <sub>x</sub> )<br>Metal oxides                                                                                                                                                                                                |
| <div></div> | Specific extinguishing methods                 | : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| <div></div> | Special protective equipment for fire-fighters | : In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.                                                                                                                                            |

### SECTION 6. ACCIDENTAL RELEASE MEASURES

|                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|---------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Personal precautions, protective equipment and emergency procedures | : Remove all sources of ignition.<br>Use personal protective equipment.<br>Follow safe handling advice and personal protective equipment recommendations.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Environmental precautions                                           | : Discharge into the environment must be avoided.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g., by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>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.<br>Soak up with inert absorbent material.<br>Suppress (knock down) gases/vapors/mists with a water spray jet.<br>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.<br>Clean up remaining materials from spill with suitable absorbent.<br>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.<br>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.                                                                                                       |
| <div></div>        | Local/Total ventilation : Use with local exhaust ventilation.<br>Use only in an area equipped with explosion-proof exhaust ventilation if advised by assessment of the local exposure |

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- potential
- Advice on safe handling : Avoid inhalation of vapor or mist.  
 Do not swallow.  
 Avoid contact with eyes.  
 Avoid prolonged or repeated contact with skin.  
 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 and sources of ignition.  
 Take precautionary measures against static discharges.  
 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  
 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

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

| Ingredients          | CAS-No.  | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | Basis     |
|----------------------|----------|----------------------------------|------------------------------------------------|-----------|
| Pentobarbital sodium | 57-33-0  | TWA                              | 40µg/m <sup>3</sup> (OEB3)                     | Merck     |
|                      |          | Wipe limit                       | 400µg/100cm <sup>2</sup>                       | Merck     |
| Propylene glycol     | 57-55-6  | TWA                              | 10 mg/m <sup>3</sup>                           | US WEEL   |
| Ethanol              | 64-17-5  | TWA                              | 1,000 ppm<br>1,900 mg/m <sup>3</sup>           | NIOSH REL |
|                      |          | STEL                             | 1,000 ppm                                      | ACGIH     |
|                      |          | TWA                              | 1,000 ppm<br>1,900 mg/m <sup>3</sup>           | OSHA Z-1  |
| Phenytoin sodium     | 630-93-3 | TWA                              | 50 µg/m <sup>3</sup> (OEB3)                    | Merck     |
|                      |          | Wipe limit                       | 500 µg/100 cm <sup>2</sup>                     | Merck     |
| Benzyl alcohol       | 100-51-6 | TWA                              | 10 ppm                                         | US WEEL   |

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**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.

**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** : Ensure that eye flushing systems and safety showers are located close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of

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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 information 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                                      | : 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)<br>Water solubility              | : No data available         |
| Partition coefficient: n-octanol/water           | : No data available         |
| Autoignition temperature                         | : No data available         |
| Decomposition temperature                        | : No data available         |

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|                      |   |                                                          |
|----------------------|---|----------------------------------------------------------|
| 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 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.<br>Vapors may form explosive mixture with air.<br>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: 298.5 mg/kg<br>Method: Calculation method                                                    |
| Acute inhalation toxicity | : | Acute toxicity estimate: > 200 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Method: Calculation method |

**Ingredients:****Pentobarbital sodium:**

|                     |   |                                                  |
|---------------------|---|--------------------------------------------------|
| Acute oral toxicity | : | LD50 (Rat): 118 mg/kg<br>LD50 (Mouse): 239 mg/kg |
|---------------------|---|--------------------------------------------------|



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LD50 (Rabbit): 175 mg/kg

LD50 (Dog): 65 mg/kg

**Propylene glycol:**

Acute oral toxicity : LD50 (Rat): &gt; 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rabbit): > 159 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mistAcute 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 401Acute inhalation toxicity : LC50 (Rat): 124.7 mg/l  
Exposure time: 4 h  
Test atmosphere: vapor**Phenytoin sodium:**

Acute oral toxicity : LD50 (Mouse): 150 - 490 mg/kg

**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.

**Ingredients:****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

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**Benzyl alcohol:**

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

**Serious eye damage/eye irritation**

Not classified based on available information.

**Ingredients:****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**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Ingredients:****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

**Benzyl alcohol:**

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

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Result: negative

**Germ cell mutagenicity**

Not classified based on available information.

**Ingredients:****Propylene glycol:**

|                       |                                                                                                                                                                        |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative                                                                                               |
| Genotoxicity in vivo  | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Intraperitoneal injection<br>Result: negative |

**Ethanol:**

|                       |                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: In vitro mammalian cell gene mutation test<br>Result: negative<br><br>Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |
| Genotoxicity in vivo  | : Test Type: Rodent dominant lethal test (germ cell) (in vivo)<br>Species: Mouse<br>Application Route: Ingestion<br>Result: equivocal                     |

**Phenytoin sodium:**

|                       |                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Result: negative<br>Remarks: Based on data from similar materials<br><br>Test Type: In vitro sister chromatid exchange assay in mammalian cells<br>Result: positive<br>Remarks: Based on data from similar materials                        |
| Genotoxicity in vivo  | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative<br>Remarks: Based on data from similar materials<br><br>Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)<br>Species: Rat<br>Application Route: Intraperitoneal injection |

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Result: negative  
Remarks: Based on data from similar materials

Test Type: Mammalian bone marrow sister chromatid exchange  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: positive  
Remarks: Based on data from similar materials

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

**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.

**Ingredients:****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: positive  
Target Organs: Liver

Species: Mouse  
Application Route: Ingestion  
Exposure time: 2 Years  
Result: positive  
Target Organs: Liver

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in animal studies

**Benzyl alcohol:**

Species: Mouse

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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.

**Ingredients:****Pentobarbital sodium:**

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

**Propylene glycol:**

Effects on fertility : Test Type: Three-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 : Species: Rat  
Application Route: Ingestion  
Fertility: LOAEL: 10 mg/kg body weight  
Result: positive

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Ingestion  
Developmental Toxicity: LOAEL: 150 mg/kg body weight

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Result: positive

Test Type: Embryo-fetal development

Species: Monkey

Application Route: Ingestion

Result: positive

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).

**Ingredients:****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.

**Ingredients:****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****Ingredients:****Propylene glycol:**

Species: Rat, male

NOAEL: 1,700 mg/kg

Application Route: Ingestion

Exposure time: 2 y

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**Ethanol:**

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

**Phenytoin sodium:**

Species: Mouse  
NOAEL: 30 mg/kg  
Application Route: Ingestion  
Exposure time: 13 Weeks  
Target Organs: Liver  
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****Ingredients:****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****Ingredients:****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

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|                                                                        |                                                                                                                       |
|------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
|                                                                        | Exposure time: 96 h                                                                                                   |
| Toxicity to daphnia and other aquatic invertebrates                    | : EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l<br>Exposure time: 48 h                                          |
| Toxicity to algae                                                      | : ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l<br>Exposure time: 7 d                                           |
| Toxicity to microorganisms                                             | : NOEC (Pseudomonas putida): > 20,000 mg/l<br>Exposure time: 18 h                                                     |

### Ethanol:

|                                                                        |                                                                                                                                                                          |
|------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish                                                       | : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l<br>Exposure time: 96 h                                                                                       |
| Toxicity to daphnia and other aquatic invertebrates                    | : EC50 (Ceriodaphnia (water flea)): > 1,000 mg/l<br>Exposure time: 48 h                                                                                                  |
| Toxicity to algae                                                      | : ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l<br>Exposure time: 72 h<br><br>EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l<br>Exposure time: 72 h |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC (Daphnia magna (Water flea)): 9.6 mg/l<br>Exposure time: 9 d                                                                                                      |
| Toxicity to microorganisms                                             | : EC50 (Pseudomonas putida): 6,500 mg/l<br>Exposure time: 16 h                                                                                                           |

### Phenytoin sodium:

#### Ecotoxicology Assessment

|                          |                                    |
|--------------------------|------------------------------------|
| Acute aquatic toxicity   | : Toxic effects cannot be excluded |
| Chronic aquatic toxicity | : Toxic effects cannot be excluded |

### Benzyl alcohol:

|                                                     |                                                                                                         |
|-----------------------------------------------------|---------------------------------------------------------------------------------------------------------|
| Toxicity to fish                                    | : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l<br>Exposure time: 96 h                          |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Daphnia magna (Water flea)): 230 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |
| Toxicity to algae                                   | : EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l                                        |



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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****Ingredients:****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

**Benzyl alcohol:**

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

**Bioaccumulative potential****Ingredients:****Propylene glycol:**

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

**Ethanol:**

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

**Benzyl alcohol:**

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

**Mobility in soil**

No data available

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**Other adverse effects**

No data available

**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

|                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                    |
|------------------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Waste from residues    | : | Dispose of in accordance with local regulations.                                                                                                                                                                                                                                                                                                                                                                   |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>Empty containers retain residue and can be dangerous.<br>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.<br>If not otherwise specified: Dispose of as unused product. |

**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

|                      |   |                                                                    |
|----------------------|---|--------------------------------------------------------------------|
| UN number            | : | UN 1992                                                            |
| Proper shipping name | : | FLAMMABLE LIQUID, TOXIC, N.O.S.<br>(Ethanol, Pentobarbital sodium) |
| Class                | : | 3                                                                  |
| Subsidiary risk      | : | 6.1                                                                |
| Packing group        | : | III                                                                |
| Labels               | : | 3 (6.1)                                                            |

**IATA-DGR**

|                                          |   |                                                                    |
|------------------------------------------|---|--------------------------------------------------------------------|
| UN/ID No.                                | : | UN 1992                                                            |
| Proper shipping name                     | : | Flammable liquid, toxic, n.o.s.<br>(Ethanol, Pentobarbital sodium) |
| Class                                    | : | 3                                                                  |
| Subsidiary risk                          | : | 6.1                                                                |
| Packing group                            | : | III                                                                |
| Labels                                   | : | Flammable Liquids, Toxic                                           |
| Packing instruction (cargo aircraft)     | : | 366                                                                |
| Packing instruction (passenger aircraft) | : | 355                                                                |

**IMDG-Code**

|                      |   |                                                                    |
|----------------------|---|--------------------------------------------------------------------|
| UN number            | : | UN 1992                                                            |
| Proper shipping name | : | FLAMMABLE LIQUID, TOXIC, N.O.S.<br>(Ethanol, Pentobarbital sodium) |
| Class                | : | 3                                                                  |
| Subsidiary risk      | : | 6.1                                                                |
| Packing group        | : | III                                                                |
| Labels               | : | 3 (6.1)                                                            |
| EmS Code             | : | F-E, S-D                                                           |
| Marine pollutant     | : | no                                                                 |

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**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      | : | UN 1992                                                             |
| Proper shipping name | : | Flammable liquids, toxic, n.o.s.<br>(Ethanol, Pentobarbital sodium) |
| Class                | : | 3                                                                   |
| Subsidiary risk      | : | 6.1                                                                 |
| Packing group        | : | III                                                                 |
| Labels               | : | FLAMMABLE LIQUID, TOXIC                                             |
| ERG Code             | : | 131                                                                 |
| Marine pollutant     | : | no                                                                  |

**SECTION 15. REGULATORY INFORMATION****EPCRA - Emergency Planning and Community Right-to-Know****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.

|                             |   |                                                              |
|-----------------------------|---|--------------------------------------------------------------|
| <b>SARA 311/312 Hazards</b> | : | Flammable (gases, aerosols, liquids, or solids)              |
|                             |   | Acute toxicity (any route of exposure)                       |
|                             |   | Carcinogenicity                                              |
|                             |   | Reproductive toxicity                                        |
|                             |   | Specific target organ toxicity (single or repeated exposure) |

|                 |   |                                                                                                      |
|-----------------|---|------------------------------------------------------------------------------------------------------|
| <b>SARA 313</b> | : | 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).

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## 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 |
|---------|---------|

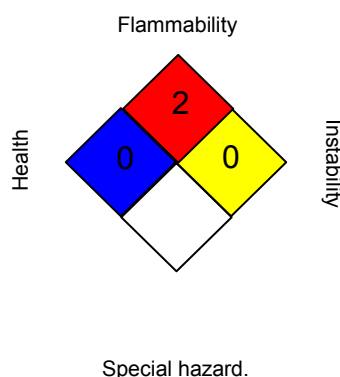
## The ingredients of this product are reported in the following inventories:

|       |   |                |
|-------|---|----------------|
| AICS  | : | not determined |
| DSL   | : | not determined |
| IECSC | : | not determined |

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA:



#### 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                                                                                  |

AICS - Australian Inventory of Chemical Substances; 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 Haz-

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ardous 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 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; 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 : 10/09/2017

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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.

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