SAFETY DATA SHEET

Pentobarbital Sodium / Phenytoin Formulation

Section 1: Identification

Product name : Pentobarbital Sodium / Phenytoin Formulation

Manufacturer or supplier’s details

Company : MSD
Address : 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Section 2: Hazard identification

GHS Classification

Flammable liquids : Category 3
Acute toxicity (Oral) : Category 3
Skin sensitisation : Category 1
Carcinogenicity (Oral) : Category 2
Reproductive toxicity : Category 2
Specific target organ toxicity - single exposure : Category 1 (Central nervous system)
Specific target organ toxicity - repeated exposure : Category 2 (Central nervous system)

GHS label elements

Hazard pictograms :
Signal word : Danger
Hazard statements : H226 Flammable liquid and vapour.
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).
H373 May cause 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, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical/ ventilating/ lighting equipment.
P242 Use non-sparking tools.
P243 Take action to prevent static discharges.
P246 Do not breathe mist or vapours.
P260 Do not eat, drink or smoke when using this product.
P264 Wash skin thoroughly after handling.
P267 Do not eat, drink or smoke when using this product.
P268 Wash skin thoroughly after handling.
P260 Do not eat, drink or smoke when using this product.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
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.
P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

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 which do not result in classification
Vapours may form explosive mixture with air.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentobarbital sodium</td>
<td>57-33-0</td>
<td>&gt;= 30 &lt; 60</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 10 &lt; 30</td>
</tr>
<tr>
<td>Ethanol#</td>
<td>64-17-5</td>
<td>&gt;= 10 &lt; 30</td>
</tr>
<tr>
<td>Phenytoin sodium</td>
<td>630-93-3</td>
<td>&gt;= 3 &lt; 10</td>
</tr>
</tbody>
</table>
Section 4: First-aid measures

<table>
<thead>
<tr>
<th>Benzyl alcohol</th>
<th>100-51-6</th>
<th>&lt; 10</th>
</tr>
</thead>
</table>

# Voluntarily-disclosed non-hazardous substance

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 centre 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. May cause damage to organs through prolonged or repeated exposure.

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

Notes to physician: Treat symptomatically and supportively.

Section 5: Fire-fighting measures

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

Unsuitable extinguishing media: High volume water jet

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

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)
Metal oxides
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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 firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Hazchem Code: 3Y

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/vapours/mists with a water spray jet. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

Section 7: Handling and storage

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

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

Advice on safe handling: Do not get on skin or clothing. Do not breathe mist or vapours. 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.

Hygiene measures:

If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.

When using do not eat, drink or smoke.

Contaminated work clothing should not be allowed out of the workplace.

Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate decontamination, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage:

Keep in properly labelled 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:

- Self-reactive substances and mixtures
- Organic peroxides
- Oxidizing agents
- Flammable gases
- Pyrophoric liquids
- Pyrophoric solids
- Self-heating substances and mixtures
- Poisonous gases
- Explosives

Section 8: Exposure controls/personal protection

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentobarbital sodium</td>
<td>57-33-0</td>
<td>TWA</td>
<td>40µg/m3 (OEL3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>400µg/100cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>WES-TWA (particulate)</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WES-TWA (Vapour and particulates)</td>
<td>150 ppm 474 mg/m³</td>
<td>NZ OEL</td>
</tr>
</tbody>
</table>
Ethanol | 64-17-5 | WES-TWA | 1,000 ppm | NZ OEL
| | | | |
| | | | |
| Phenytoin sodium | 630-93-3 | TWA | 50 µg/m³ (OEB3) | Internal
| | | | |
| | | | |

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

Personal protective equipment
Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type: Combined particulates and organic vapour type
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.

Section 9: Physical and chemical properties
Appearance: liquid
Colour: pink
Odour: No data available
Odour Threshold: No data available
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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
Vapour pressure : No data available
Relative vapour 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
Auto-ignition 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 size : No data available

Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard.
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Version 5.1  Revision Date: 27.08.2021  SDS Number: 671676-00016  Date of last issue: 09.04.2021

Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions:
- Flammable liquid and vapour.
- Vapours 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

Exposure routes:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Toxic if swallowed.

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

Acute inhalation toxicity:
- Acute toxicity estimate: > 5 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: Calculation method

Components:

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

Propylene glycol:
Acute oral toxicity:
- LD50 (Rat): 22,000 mg/kg

Acute inhalation toxicity:
- LC50 (Rat): > 44.9 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist

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

Ethanol:
Acute oral toxicity:
- LD50 (Rat): > 5,000 mg/kg
  Method: OECD Test Guideline 401
Acute inhalation toxicity: LC50 (Rat): 124.7 mg/l
Exposure time: 4 h
Test atmosphere: vapour

Phenytoin sodium:
Acute oral toxicity: Acute toxicity estimate: 100 mg/kg
Method: Expert judgement

Benzyl alcohol:
Acute oral toxicity: LD50 (Rat): 1,620 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 4.178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Skin corrosion/irritation
Not classified based on available information.

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

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

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

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

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

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

Respiratory or skin sensitisation

Skin sensitisation
May cause an allergic skin reaction.

Respiratory sensitisation
Not classified based on available information.

Components:

Propylene glycol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Ethanol:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Result: negative

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

Benzy alcohol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Chronic toxicity

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
<table>
<thead>
<tr>
<th>Substance</th>
<th>Genotoxicity in vitro</th>
<th>Genotoxicity in vivo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity in vivo</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>Test Type: Rodent dominant lethal test (germ cell) (in vivo)</td>
</tr>
<tr>
<td></td>
<td>Species: Mouse</td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intraperitoneal injection</td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Result: equivocal</td>
</tr>
<tr>
<td>Genotoxicity in vitro</td>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Result: negative</td>
</tr>
<tr>
<td>Genotoxicity in vivo</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Test Type: Chromosome aberration test in vitro</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Test Type: In vitro sister chromatid exchange assay in mammalian cells</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Result: positive</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Species: Mouse</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Application Route: Intraperitoneal injection</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td>Result: negative</td>
</tr>
<tr>
<td>Genotoxicity in vitro</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
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<td>Result: negative</td>
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<td>Species: Mouse</td>
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<td>Application Route: Intraperitoneal injection</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

**Carcinogenicity**

Suspected of causing cancer if swallowed.
Components:

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

Phenytoin sodium:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative
Species: Mouse
Application Route: Ingestion
Exposure time: 2 Years
Result: positive

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

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

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 foetal development: Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

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

Phenytoin sodium:

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

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

STOT - single exposure
Causes damage to organs (Central nervous system).

Components:

Pentobarbital sodium:

Exposure routes: Ingestion
Target Organs: Central nervous system
Assessment: Causes damage to organs.

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

Components:

Phenytoin sodium:

Exposure routes: Ingestion
Target Organs: Central nervous system
Assessment: Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.
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Pentobarbital Sodium / Phenytoin Formulation

Revised: 27.08.2021

Version 5.1

SDS Number: 671676-00016

Date of last issue: 09.04.2021
Date of first issue: 12.05.2016

Repeated dose toxicity

Components:

Propylene glycol:
Species: Rat, male
NOAEL: >= 1,700 mg/kg
Application Route: Ingestion
Exposure time: 2 yr

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

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

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

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

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

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

Phenytoin sodium:
Ingestion: Symptoms: Nausea, constipation, confusion, Vomiting, central nervous system effects, Dizziness, insomnia, Blood disorders, Liver disorders, Tremors, anorexia
Section 12: Ecological information

Ecotoxicity

**Components:**

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

**Propylene glycol:**
- **Toxicity to fish:** LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
  Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates:** EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
  Exposure time: 48 h
- **Toxicity to algae/aquatic plants:** ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):** NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
  Exposure time: 7 d

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

**Phenytoin sodium:**
- **Toxicity to fish:** EC50 (Danio rerio (zebra fish)): > 10 - 100 mg/l
  Exposure time: 72 h
  Remarks: Based on data from similar materials
- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):** NOEC (Daphnia magna (Water flea)): 9.6 mg/l
  Exposure time: 9 d
- **Toxicity to microorganisms:** EC50 (Pseudomonas putida): 6,500 mg/l
  Exposure time: 16 h

Remarks: Based on data from similar materials

No toxicity at the limit of solubility
aquatic invertebrates

**Benzyl alcohol:**

Toxicity to fish: $\text{LC50 (Pimephales promelas (fathead minnow)): 460 mg/l}$

Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: $\text{EC50 (Daphnia magna (Water flea)): 230 mg/l}$

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: $\text{EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l}$

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): $\text{NOEC (Daphnia magna (Water flea)): 51 mg/l}$

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-octanol/water: \( \log Pow = -1.07 \)

**Ethanol:**
- Partition coefficient: n-octanol/water: \( \log Pow = -0.35 \)

**Phenytoin sodium:**
- Partition coefficient: n-octanol/water: \( \log Pow = 2.84 \)
- Remarks: Calculation

**Benzyl alcohol:**
- Partition coefficient: n-octanol/water: \( \log Pow = 1.05 \)

**Mobility in soil:**
- No data available

**Other adverse effects:**
- No data available

Section 13: Disposal considerations

**Disposal methods:**
- Waste from residues: Dispose of in accordance with local regulations.
- 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

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

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

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

**National Regulations**

**NZS 5433**
UN number: UN 1993
Proper shipping name: FLAMMABLE LIQUID, N.O.S. (Ethanol, Pentobarbital sodium)
Class: 3
Packing group: III
Labels: 3
Hazchem Code: 3Y

**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**

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

**HSNO Approval Number**
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

**HSW Controls**
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

**The components of this product are reported in the following inventories:**
AICS: not determined
SAFETY DATA SHEET

Pentobarbital Sodium / Phenytoin Formulation

Section 16: Other information

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
NZ OEL: New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / STEL: Short-term exposure limit
NZ OEL / WES-TWA: Workplace Exposure Standard - Time Weighted average

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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