

SAFETY DATA SHEET



Pentobarbital Sodium / Phenytoin Formulation

Version 8.2 Revision Date: 28.09.2024 SDS Number: 671676-00022 Date of last issue: 30.09.2023
Date of first issue: 12.05.2016

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 : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800 CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

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)

Hazardous to the aquatic environment - chronic hazard : Category 3

GHS label elements

Pentobarbital Sodium / Phenytoin Formulation

Version 8.2	Revision Date: 28.09.2024	SDS Number: 671676-00022	Date of last issue: 30.09.2023 Date of first issue: 12.05.2016
----------------	------------------------------	-----------------------------	---

Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	<p>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. H412 Harmful to aquatic life with long lasting effects.</p>
Precautionary statements	:	<p>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. P260 Do not breathe mist or vapours. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P272 Contaminated work clothing should not be allowed out of the workplace. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.</p> <p>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.</p> <p>Storage: P403 + P235 Store in a well-ventilated place. Keep cool. P405 Store locked up.</p> <p>Disposal: P501 Dispose of contents/ container to an approved waste</p>

SAFETY DATA SHEET



Pentobarbital Sodium / Phenytoin Formulation

Version
8.2

Revision Date:
28.09.2024

SDS Number:
671676-00022

Date of last issue: 30.09.2023
Date of first issue: 12.05.2016

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

Components

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	>= 1 -< 10
Benzyl alcohol	100-51-6	>= 1 -< 10

Voluntarily-disclosed substance

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.

In case of eye contact : Thoroughly clean shoes before reuse.
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

Pentobarbital Sodium / Phenytoin Formulation

Version 8.2	Revision Date: 28.09.2024	SDS Number: 671676-00022	Date of last issue: 30.09.2023 Date of first issue: 12.05.2016
----------------	------------------------------	-----------------------------	---

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) 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 (NO _x) 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 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

Pentobarbital Sodium / Phenytoin Formulation

Version 8.2	Revision Date: 28.09.2024	SDS Number: 671676-00022	Date of last issue: 30.09.2023 Date of first issue: 12.05.2016
----------------	------------------------------	-----------------------------	---

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 degowning and decontamination procedures, 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.

SAFETY DATA SHEET



Pentobarbital Sodium / Phenytoin Formulation

Version
8.2

Revision Date:
28.09.2024

SDS Number:
671676-00022

Date of last issue: 30.09.2023
Date of first issue: 12.05.2016

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

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Pentobarbital sodium	57-33-0	TWA	40µg/m3 (OEB3)	Internal
		Wipe limit	400µg/100cm ²	Internal
Propylene glycol	57-55-6	WES-TWA (particulate)	10 mg/m ³	NZ OEL
		WES-TWA (Vapour and particulates)	150 ppm 474 mg/m ³	NZ OEL
Ethanol	64-17-5	WES-TWA	200 ppm 380 mg/m ³	NZ OEL
		Further information: Ototoxin		
		WES-STEL	800 ppm 1,520 mg/m ³	NZ OEL
		Further information: Ototoxin		
		STEL	1,000 ppm	ACGIH
Phenytoin sodium	630-93-3	TWA	50 µg/m ³ (OEB3)	Internal
		Wipe limit	500 µg/100 cm ²	Internal

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

Pentobarbital Sodium / Phenytoin Formulation

Version 8.2 Revision Date: 28.09.2024 SDS Number: 671676-00022 Date of last issue: 30.09.2023
Date of first issue: 12.05.2016

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

SAFETY DATA SHEET



Pentobarbital Sodium / Phenytoin Formulation

Version 8.2 Revision Date: 28.09.2024 SDS Number: 671676-00022 Date of last issue: 30.09.2023
Date of first issue: 12.05.2016

flammability limit

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	: No data available
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 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 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
-----------------	--

Pentobarbital Sodium / Phenytoin FormulationVersion
8.2Revision Date:
28.09.2024SDS Number:
671676-00022Date of last issue: 30.09.2023
Date of first issue: 12.05.2016**Acute toxicity**

Toxic if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 261.66 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg
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): 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: vapour

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

Phenytoin sodium:

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

Benzyl alcohol:

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

Pentobarbital Sodium / Phenytoin Formulation

Version 8.2	Revision Date: 28.09.2024	SDS Number: 671676-00022	Date of last issue: 30.09.2023 Date of first issue: 12.05.2016
----------------	------------------------------	-----------------------------	---

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

Acute dermal toxicity : Acute toxicity estimate: 1,100 mg/kg
Method: Expert judgement
Remarks: Based on national or regional regulation.

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

Pentobarbital Sodium / Phenytoin Formulation

Version 8.2 Revision Date: 28.09.2024 SDS Number: 671676-00022 Date of last issue: 30.09.2023
Date of first issue: 12.05.2016

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 : Mouse ear swelling test (MEST)
Exposure routes : Skin contact
Species : Mouse
Result : negative

Phenytoin sodium:

Assessment : Probability or evidence of skin sensitisation in humans

Benzyl alcohol:

Test Type : Human repeat insult patch test (HRIPT)
Exposure routes : Skin contact
Species : Humans
Result : positive

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

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

Pentobarbital Sodium / Phenytoin Formulation

Version 8.2	Revision Date: 28.09.2024	SDS Number: 671676-00022	Date of last issue: 30.09.2023 Date of first issue: 12.05.2016
----------------	------------------------------	-----------------------------	---

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:

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

Pentobarbital Sodium / Phenytoin Formulation

Version 8.2	Revision Date: 28.09.2024	SDS Number: 671676-00022	Date of last issue: 30.09.2023 Date of first issue: 12.05.2016
----------------	------------------------------	-----------------------------	---

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

Carcinogenicity

Suspected of causing cancer if swallowed.

Components:**Propylene glycol:**

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

Phenytoin sodium:

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

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

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

Benzyl alcohol:

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

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

SAFETY DATA SHEET



Pentobarbital Sodium / Phenytoin Formulation

Version 8.2 Revision Date: 28.09.2024 SDS Number: 671676-00022 Date of last issue: 30.09.2023
Date of first issue: 12.05.2016

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
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

Pentobarbital Sodium / Phenytoin Formulation

Version 8.2 Revision Date: 28.09.2024 SDS Number: 671676-00022 Date of last issue: 30.09.2023
Date of first issue: 12.05.2016

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

Repeated dose toxicity**Components:****Propylene glycol:**

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

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

SAFETY DATA SHEET



Pentobarbital Sodium / Phenytoin Formulation

Version 8.2 Revision Date: 28.09.2024 SDS Number: 671676-00022 Date of last issue: 30.09.2023
Date of first issue: 12.05.2016

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

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

Pentobarbital Sodium / Phenytoin Formulation

Version 8.2	Revision Date: 28.09.2024	SDS Number: 671676-00022	Date of last issue: 30.09.2023 Date of first issue: 12.05.2016
----------------	------------------------------	-----------------------------	---

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 5,012 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 fish (Chronic toxicity) : NOEC (Oryzias latipes (Japanese medaka)): >= 79 mg/l
Exposure time: 100 d

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 (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 aquatic invertebrates : Remarks: No toxicity at the limit of solubility

Benzyl alcohol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 230 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 51 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

SAFETY DATA SHEET



Pentobarbital Sodium / Phenytoin Formulation

Version 8.2 Revision Date: 28.09.2024 SDS Number: 671676-00022 Date of last issue: 30.09.2023
Date of first issue: 12.05.2016

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
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

Pentobarbital Sodium / Phenytoin Formulation

Version 8.2 Revision Date: 28.09.2024 SDS Number: 671676-00022 Date of last issue: 30.09.2023
Date of first issue: 12.05.2016

Other adverse effects

No data available

Section 13: Disposal considerations**Disposal methods**

Waste from residues : Do not dispose of waste into sewer.
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
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
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.

SAFETY DATA SHEET



Pentobarbital Sodium / Phenytoin Formulation

Version 8.2	Revision Date: 28.09.2024	SDS Number: 671676-00022	Date of last issue: 30.09.2023 Date of first issue: 12.05.2016
----------------	------------------------------	-----------------------------	---

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
Marine pollutant	:	no

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

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

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

DSL : not determined

IECSC : not determined

Section 16: Other information

Revision Date : 28.09.2024

Further information

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

SAFETY DATA SHEET



Pentobarbital Sodium / Phenytoin Formulation

Version 8.2	Revision Date: 28.09.2024	SDS Number: 671676-00022	Date of last issue: 30.09.2023 Date of first issue: 12.05.2016
----------------	------------------------------	-----------------------------	---

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
NZ OEL / WES-STEL	: Workplace Exposure Standard - Short-Term Exposure Limit

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); EC_x - Concentration associated with x% response; EL_x - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErC_x - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; 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; KECL - 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.

SAFETY DATA SHEET



Pentobarbital Sodium / Phenytoin Formulation

Version
8.2

Revision Date:
28.09.2024

SDS Number:
671676-00022

Date of last issue: 30.09.2023
Date of first issue: 12.05.2016

NZ / EN