SAFETY DATA SHEETS

This SDS packet was issued with item:

078073963

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078240220

Merck Animal Health
One Merck Dr.
Whitehouse Station, NJ 08889

MATERIAL SAFETY DATA SHEET

Merck Animal Health urges each user or recipient of this MSDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

MSDS NAME: **Beuthanasia-D Solution**

SYNONYM(S): Beuthanasia-D Special
Beuthanasia-D Injection

MSDS NUMBER: SP000354

EMERGENCY NUMBER(S): (908) 423-6000 (24/7/365) English Only

Transportation Emergencies - CHEMTREC:
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)

Rocky Mountain Poison Center (For Human Exposure):
(303) 595-4869

Animal Health Technical Services:
For Animal Adverse Events: Small Animals and Horses: (800) 224-5318
For Animal Adverse Events: Livestock: (800) 211-3573
For Animal Adverse Events: Poultry: (800) 219-9286

INFORMATION: Animal Health Technical Services:
For Small Animals and Horses: (800) 224-5318
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For Poultry: (800) 219-9286

MERCK MSDS HELPLINE: (800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Solution
Clear, Pink
Odor unknown
Toxic if swallowed.
May be toxic by inhalation.
May cause allergic reactions in susceptible individuals.
Prolonged exposure may cause serious health effects.
Causes effects to:
central nervous system
respiratory system
brain
cardiovascular system
Causes birth defects.
May cause effects to:
gastrointestinal tract
blood
immune system
liver
kidney
Harmful to fish and aquatic organisms.

POTENTIAL HEALTH EFFECTS:

The following summary is based upon available information about the individual ingredients of the mixture, or of the expected properties of the mixture. Only information about the ingredients that are expected to contribute significantly to the potential health hazard profile of the formulation(s) are presented.

This product is intended to cause euthanasia in dogs upon administration intravenously. Euthanasia is due to cerebral death in conjunction with respiratory arrest and circulatory collapse. Central nervous system depression and hypotension may also occur.

Pentobarbital sodium is a short-acting barbiturate used as a sedative, preanesthetic, and sleeping aid. Barbiturates may be habit-forming, and tolerance, psychological, or physical dependence may occur especially following prolonged use of high concentrations. Barbiturates are central nervous system and respiratory depressants. Effects that may be seen following acute exposure include slurred speech, confusion, poor judgement, irritability, insomnia, or incoordination. Effects that may be seen following exposure to high concentrations include severe confusion, decrease or loss of reflexes, severe drowsiness, fever, hypothermia, shortness of breath or troubled breathing, slow heartbeat, severe weakness, respiratory depression, pneumonia, congestive heart failure, renal failure, coma, respiratory arrest, or death.

Barbiturates readily cross the placenta following oral administration. Barbiturates have been associated with an increased risk of congenital heart disease, facial abnormalities, and other birth defects; however, no effects have been observed in women exposed to pentobarbital. In addition, newborns that were chronically exposed to bariturates in utero may exhibit withdrawl symptoms such as hyperactivity and tremors.

Phenytoin, often administered as phenytoin sodium, is an anticonvulsant and antiarrhythmic agent. Phenytoin is a central nervous system depressant. Acute effects from exposure may include nausea, vomiting, gastrointestinal pain, loss of appetite, dizziness, staggering, blurred vision, nystagmus (involuntary movement of the eye), drowsiness, pupil dilation, hyperactive tendon reflexes, tremor, increased or decreased activity, hallucinations, confusion, respiratory depression, breathing difficulties, or coma. Hypersensitivity reactions, sometimes fatal, have been reported after chronic therapy. General symptoms of potential reactions include fever, general discomfort, rash, facial swelling, skin redness, lymph node effects, hepatitis, anemia, pharyngitis, diarrhea, anorexia, kidney inflammation, and acute inflammation of the lungs. Phenytoin may also invoke autoimmune dysfunction, swelling of the gums, psychological disorders, or effects on the liver or blood.

Phenytoin freely pases through the placenta. Human teratogenicity (birth defects) has been reported in women who received phenytoin treatment, and phenytoin has been linked to Fetal Hydantoin Syndrome (FHS). Phenytoin is a teratogen in animals.

Propylene glycol is considered to be relatively non-toxic. It is a mild irritant to the eyes and has been reported to irritate the skin. It may cause skin sensitization resulting in allergic contact dermatitis in susceptible individuals. Inhalation exposure to saturated and supersaturated atmospheres of propylene glycol for prolonged periods of time produced no adverse effects. Propylene glycol may cause nervous system depression, acidosis, stupor, and seizures after chronic ingestion.

LISTED CARCINOGENS

INGREDIENT	CAS NUMBER	OSHA	IARC	NTP	ACGIH

Phenytoin Sodium	630-93-3		2B		
Ethyl Alcohol	64-17-5			K	A3

Phenytoin: IARC has classified phenytoin as a Group 2B (possibly carcinogenic to humans).

Ethanol (ethyl alcohol): IARC (International Agency for Research on Cancer) has classified Alcoholic Beverages as Group 1 (indicating in their evaluation that the agent is carcinogenic to humans). However, occupational handling or manufacturer's specified use of this product is not expected to result in relevant exposures.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

PRODUCT USE: Veterinary product

CHEMICAL FORMULA: Mixture.

The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed. For additional information about carcinogenic ingredients see Section 2.

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	PERCENT
Pentobarbital Sodium	57-33-0	39
Phenytoin Sodium	630-93-3	5
Propylene Glycol	57-55-6	10-20
Ethyl Alcohol	64-17-5	<10
Benzyl Alcohol	100-51-6	<10

ADDITIONAL INFORMATION: This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

SECTION 4. FIRST AID MEASURES

INHALATION: Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a physician.

SKIN CONTACT: In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

EYE CONTACT: In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.

INGESTION: DO NOT induce vomiting. Do not attempt to give anything by mouth to a seizing, drowsy or unconscious person. If alert, rinse mouth, drink a glass of water and IMMEDIATELY consult a physician.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

Flash Point: Not determined (liquids) or not applicable (solids).

SPECIAL FIRE FIGHTING PROCEDURES:
Wear full protective clothing and self-contained breathing apparatus (SCBA).

SUITABLE EXTINGUISHING MEDIA:
Carbon dioxide (CO2), extinguishing powder or water spray.

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:
Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

SPILL RESPONSE / CLEANUP:
All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7. HANDLING AND STORAGE

HANDLING:
Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

STORAGE:
Store in a cool, dry, well ventilated area.

See Section 8 for exposure controls and additional safe handling information.

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

The following guidance applies to the handling of the active ingredient(s) in this formulation.

OCCUPATIONAL EXPOSURE BAND (OEB):
Pentobarbital: OEB 4: 1-10 mcg/m^3. Materials in an OEB 4 category are considered high health hazards. The OEB is range of airborne concentrations expressed as an 8-hour Time Weighted Average (8-hr. TWA) and is intended to be used with Industrial Hygiene Risk Assessment to assist with industrial hygiene sampling and selection of proper controls for worker protection. Consult your site safety and industrial hygiene staff for guidance on handling and control strategies.

Phenytoin Sodium: OEB 3: 10-100 mcg/m^3. Materials in an OEB 3 category are considered moderate health hazards. The OEB is a range of airborne concentrations expressed as an 8-hour Time Weighted Average (8-hr. TWA) and is intended to be used with Industrial Hygiene Risk Assessment to assist with industrial hygiene sampling and selection of proper controls for worker protection. Consult your site safety and industrial hygiene staff for guidance on handling and control strategies.

HHC/OEG NOTATION(S):
Phenytoin Sodium: This material has a notation of "A" for its ability to cause immediate allergic hypersensitivity reactions or anaphylaxis.

EXPOSURE CONTROLS
The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Respiratory Protection:	Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.
Skin Protection:	Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.

Eye Protection: Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.

Body Protection: In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

EXPOSURE LIMIT VALUES

INGREDIENT	CAS NUMBER	ACGIH TLV (TWA)	OSHA PEL (TWA)
Ethyl Alcohol	64-17-5		1000 ppm 1900 mg/m^3

INGREDIENT	CAS NUMBER	ACGIH TLV (STEL / SKIN)	ACGIH TLV (CEIL)	OSHA PEL (STEL / SKIN)	OSHA PEL (CEIL)
Ethyl Alcohol	64-17-5	1000 ppm			

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Solution
COLOR: Clear, Pink
ODOR: Odor unknown
SOLUBILITY:
Water: Not determined

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:
Open flames and high temperatures.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
Carbon oxides (COx).

SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below pertains to the following individual ingredients in this formulation, unless indicated otherwise.

ACUTE TOXICITY DATA

INHALATION:
Propylene glycol caused no adverse effects in monkeys or rats following exposure to saturated atmospheres for prolonged periods of time.

SKIN:
Propylene glycol: Dermal LD50: 20.8 g/kg (rabbit)
Propylene glycol was irritating in a human patch test. Propylene glycol was not irritating to the skin of rabbits, guinea pigs and swine.

EYE:
Propylene glycol was slightly irritating to the eyes of rabbits.

ORAL:
Pentobarbital Sodium: Oral LD50: 118 mg/kg (rat); 65 mg/kg (dog)

Phenytoin Sodium: Oral LD50: 1530 mg/kg (rat); 165-490 mg/kg (mouse)
Toxic doses of phenytoin sodium in animals produce mydriasis, nystagmus, salivation, incoordination, and ataxia. Muscular spasticity, rigidity, tremors, convulsive movements, and opisthotonos has preceded death from respiratory failure.

Propylene glycol: Oral LD50: 21 to 33.7 g/kg (rat), 10 to 20 g/kg (dog)
Propylene glycol caused dyspnea, cramps, loss of equilibrium, depression, analgesia, and death after prolonged moribund state in mice at doses ranging from 23.9 to 31.8 g/kg. In rabbits, 1 to 1.5 g/kg propylene glycol reduced intraocular pressure by raising the osmotic pressure of blood.

DERMAL AND RESPIRATORY SENSITIZATION:
Propylene glycol did not cause sensitization in a human patch test.

ADDITIONAL INFORMATION:
This product is intended for euthansia in dogs upon intravenous administration. Cerebral death in conjunction with respiratory arrest and circulatory collapse is expected.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
Phenytoin effected the peripheral nervous system when given to female rats orally at doses of 300 mg/jg/day for 180 days. Increased thickness of craniofacial bones measured by increases of histomorphometric (osteoblast number, bone mineral apposition rate) and biochemical (skeletal alkaline phosphatase activity, osteocalcin concentrations) parameters of bone formation were observed in rats given phenytoin at doses of 5 mg/kg/day for 36 days by intraperitoneal injection.

Propylene glycol caused no adverse effects in monkeys or rats exposed to saturated vapor concentrations for 12 to 18 months. Rats exposed to 25 or 50% (7.7 and 13.2 g/kg/day) propylene glycol in water died within 69 days in a 140 day study. In a separate study, a diet of 30% propylene glycol was not well tolerated in young rats, and dams could not bring their young to weaning; diets containing 40, 50, or 60% propylene glycol were lethal after a few days.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
Pentobarbital (base) induced a number of anomalies in mice; however, it was not shown to be teratogenic in rats, rabbits, or guinea pigs.

Phenytoin is a teratogen and fetotoxin in rats. It is a teratogen in mice and rabbits, and fetotoxic in monkeys at doses that were also maternally toxic. Phenytoin is not teratogenic in dogs or cats.

Rabbits were administered phenytoin sodium by oral gavage at doses of 150 mg/kg on gestation day 14-16 or 300 mg/kg on gestation days 15-16. Fetuses were examined shortly after the last dose on Day 16. The following effects were observed in the fetuses: digital areas of the limb plates showed edema and dilated blood vessels, vascular disruption occurred with hemorrhages, mesenchymal necrosis, amputation of digits, superficial hemorrhage in the frontal and nasal region, and intracranial and superficial hemorrhage in the central nevous system. Rats were administered phenytoin sodium through intraperitoneal injections at doses of 10, 50, or 100 mg/kg on Day 17 of gestation. There were no adverse effects on pregnancy or neonatal survival in the 10 and 50 mg/kg group. In the 100 mg/kg group, total fetal loss was observed in 50% of the dams, and in the remaining dams, delivery was delayed. In monkeys, oral administration of 60 to 600 mg/kg of phenytoin during gestational days 21 to 50 resulted in dose dependent maternal toxicity, and an increase in embryonic loss. In mice, phenytoin induced cleft palated when administered subcutaneously at doses up to 50 mg/kg from days 9 to 15 of gestation.

Propylene glycol caused decreased food consumption, retarded growth, smaller litters, changes in breeding patterns, and inhibited weaning in rats that were fed 30% propylene glycol through six generations; however, this may have been due to nutritional insufficiency. Propylene glycol was not teratogenic in rabbits, monkeys or chickens.

MUTAGENICITY / GENOTOXICITY:
Pentobarbital (base) was positive in the mouse micronucleus assay, mouse cell DNA inhibition test, hamster cytogenetic assay, and in the hamster dominant lethal test.

Studies with phenytoin showed no induction of micronuclei, chromosomal aberrations, or aneuploidy in human lymphocytes in vivo. There was an increase of polyploidy in one study, and sister chromatid exchange in three of seven studies. Neither chromosomal aberrations nor aneuploidy were induced in human bone marrow. Phenytoin induced mutations in Salmonella typhimurium in the presence of a metabolic activation system in one study, but was negative in Drosophila or mammalian cells in vitro assays in the absence of a metabolic system. Aneuploidy was induced in one study in primary mouse embryonic fibroblasts in vitro. Cell transformation was induced in Syrian hamster embryo. Phenytoin inhibited gap-junctional intercellular communication.

Propylene glycol was negative in a bacterial mutagenicity study (Ames).

CARCINOGENICITY:
This material or product has not been evaluated for carcinogenicity.

IARC has classified phenytoin as a Group 2B (agent is a possible human carcinogen) based on sufficient evidence in animals.

Phenytoin sodium was tested in three strains of mice at oral doses of 60 mg/kg/day for 168 days. There was an increase of thymic lymphomas in two strains of mice, and in the other strain, there was an increase of generatlized lymphomas. In another study, mice administered intraperitoneal injections of 0.6 mg/mouse over 66 days showed an increase in tumors: thymic, mesenteric, and leukemia.

Propylene glycol was not carcinogenic when applied to the skin, or when given orally in mice and rats.

SECTION 12. ECOLOGICAL INFORMATION

There are no data for the final product or its formulation(s). The information presented below pertains to the following ingredient(s).

ECOTOXICITY DATA

INGREDIENT ECOTOXICITY

Pentobarbital Sodium: 96-hr LC50 (fathead minnow): 49.5 mg/L

Propylene glycol: 96-hr LC50 (sheepshead minnow): 23,800 mg/L
Propylene glycol: 48-hr EC50 (daphnid): >43,500 mg/L
Propylene glycol: 72-hr EC50 (green algae): >19,000 mg/L

ENVIRONMENTAL DATA

OTHER INGREDIENT ENVIRONMENTAL DATA:

Propylene glycol is expected to be readily biodegradable.

SECTION 13. DISPOSAL CONSIDERATIONS

MATERIAL WASTE:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

SECTION 14. TRANSPORT INFORMATION

This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

SECTION 15. REGULATORY INFORMATION

TSCA LISTING

INGREDIENT	TSCA
Phenytoin Sodium	X
Propylene Glycol	X
Ethyl Alcohol	X
Benzyl Alcohol	X

U.S. STATE REGULATIONS

INGREDIENT	California Proposition 65	CARTK	NJRTK	CTRTK	MARTK
Pentobarbital Sodium	D		3726		
Phenytoin Sodium	C	X			
Propylene Glycol			3595		
Ethyl Alcohol	C D	X	0844		X
Benzyl Alcohol					X

INGREDIENT	PARTK	MNRTK	MIRTK	RIRTK
Phenytoin Sodium	X	X		

INGREDIENT	PARTK	MNRTK	MIRTK	RIRTK
Propylene Glycol	X	X		X
Ethyl Alcohol	X	X		X
Benzyl Alcohol	X	X		

SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

DEPARTMENT ISSUING MSDS:
Global Safety & the Environment
Merck & Co., Inc.
One Merck Drive
Whitehouse Station, NJ 08889

MERCK MSDS HELPLINE:
(800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

MSDS CREATION DATE: 03-Mar-1992

SUPERSEDES DATE: 03-Sep-2009

SECTIONS CHANGED (US SUBFORMAT): 14
SIGNIFICANT CHANGES (US SUBFORMAT): Transportation, OEB

Merck Animal Health
One Merck Dr.
Whitehouse Station, NJ 08889

SAFETY DATA SHEET

Merck Animal Health urges each user or recipient of this MSDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

PRODUCT IDENTIFIER

SDS NAME: **Beuthanasia-D Solution**

SYNONYM(S): Beuthanasia-D Special
Beuthanasia-D Injection

SDS Number: SP000354

RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

IDENTIFIED USE(S): Veterinary Product

USE(S) ADVISED AGAINST: None known.

DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

US SUPPLIER: Merck Animal Health
One Merck Dr.
Whitehouse Station, NJ 08889

INFORMATION: Animal Health Technical Services:
For Small Animals and Horses: (800) 224-5318
For Livestock: (800) 211-3573
For Poultry: (800) 219-9286

MERCK SDS HELPLINE: (800) 770-8878 (US and Canada)
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Monday to Friday, 9am to 5pm (US Eastern Time)

SDS EMAIL: mercksds@merck.com

EMERGENCY TELEPHONE NUMBER

EMERGENCY NUMBER(S): (908) 423-6000 (24/7/365) English Only

Transportation Emergencies - CHEMTREC:
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)
Rocky Mountain Poison Center (For Human Exposure):
(303) 595-4869

Animal Health Technical Services:
For Animal Adverse Events: Small Animals: (800) 224-5318
For Animal Adverse Events: Equine: (866) 349-3497
For Animal Adverse Events: Livestock: (800) 211-3573
For Animal Adverse Events: Poultry: (800) 219-9286

SECTION 2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the OSHA Hazard Communication standard 2012 (29 CFR 1910.1200)

Category 3	Flammable liquids

GHS Label elements, including precautionary statements

Emergency Overview

Signal Word **Warning**

Physical Hazard Statements
- Flammable liquid and vapor

COLOR: Clear, Pink **FORM:** Solution **ODOR:** Odor unknown

Precautionary Statements

Prevention
- P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
- P240 - Ground/bond container and receiving equipment
- P241 - Use explosion-proof electrical/ ventilating/ lighting/ equipment
- P242 - Use only non-sparking tools
- P243 - Take precautionary measures against static discharge
- P280 - Wear protective gloves/ protective clothing/ eye protection/ face protection

Skin
- P303 + P361 + P353 - IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower

Fire
- P370 + P378 - In case of fire: Use water spray for extinction

Storage
- P403 + P235 - Store in a well-ventilated place. Keep cool

Disposal
- P501 - Dispose of contents/ container to an approved waste disposal plant

Hazard Not Otherwise Classified (HNOC)

Other information

Causes effects to:
central nervous system
respiratory system
brain
cardiovascular system
Causes birth defects.
May cause effects to:
gastrointestinal tract
blood
immune system
liver
kidney

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

CHEMICAL FORMULA: Mixture.

The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed. For additional information about carcinogenic ingredients see Section 2.

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	PERCENT	TRADE SECRET
Pentobarbital Sodium	57-33-0	39	
Propylene Glycol	57-55-6	10-20	
Ethyl Alcohol	64-17-5	<10	
Phenytoin Sodium	630-93-3	5	
Benzyl Alcohol	100-51-6	<10	

ADDITIONAL INFORMATION: This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

SECTION 4. FIRST AID MEASURES

FIRST AID MEASURES

INHALATION: Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a physician.

SKIN CONTACT: In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

EYE CONTACT: In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.

INGESTION: DO NOT induce vomiting. Do not attempt to give anything by mouth to a seizing, drowsy or unconscious person. If alert, rinse mouth, drink a glass of water and IMMEDIATELY consult a physician.

FIRST AID RESPONDER PROTECTION: Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves with appropriate personal protective equipment. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. DO NOT use mouth-to-mouth method if victim ingested or inhaled the substance.

MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

The following summary is based upon available information about the individual ingredients of the mixture, or of the expected properties of the mixture. Only information about the ingredients that are expected to contribute significantly to the potential health hazard profile of the formulation(s) are presented.

This product is intended to cause euthanasia in dogs upon administration intravenously. Euthanasia is due to cerebral death in conjunction with respiratory arrest and circulatory collapse. Central nervous system depression and hypotension may also occur.

Pentobarbital sodium is a short-acting barbiturate used as a sedative, preanesthetic, and sleeping aid. Barbiturates may be habit-forming, and tolerance, psychological, or physical dependence may occur especially following prolonged use of high concentrations. Barbiturates are central nervous system and respiratory depressants. Effects that may be seen following acute exposure include slurred speech, confusion, poor judgement, irritability, insomnia, or incoordination. Effects that may be seen following exposure to high concentrations include severe confusion, decrease or loss of reflexes, severe drowsiness, fever, hypothermia, shortness of breath or troubled breathing, slow heartbeat, severe weakness, respiratory depression, pneumonia, congestive heart failure, renal failure, coma, respiratory arrest, or death.

Barbiturates readily cross the placenta following oral administration. Barbiturates have been associated with an increased risk of congenital heart disease, facial abnormalities, and other birth defects; however, no effects have been observed in women exposed to pentobarbital. In addition, newborns that were chronically exposed to bariturates in utero may exhibit withdrawl symptoms such as hyperactivity and tremors.

Phenytoin, often administered as phenytoin sodium, is an anticonvulsant and antiarrhythmic agent. Phenytoin is a central nervous system depressant. Acute effects from exposure may include nausea, vomiting, gastrointestinal pain, loss of appetite, dizziness, staggering, blurred vision, nystagmus (involuntary movement of the eye), drowsiness, pupil dilation, hyperactive tendon reflexes, tremor, increased or decreased activity, hallucinations, confusion, respiratory depression, breathing difficulties, or coma. Hypersensitivity reactions, sometimes fatal, have been reported after chronic therapy. General symptoms of potential reactions include fever, general discomfort, rash, facial swelling, skin redness, lymph node effects, hepatitis, anemia, pharyngitis, diarrhea, anorexia, kidney inflammation, and acute inflammation of the lungs. Phenytoin may also invoke autoimmune dysfunction, swelling of the gums, psychological disorders, or effects on the liver or blood.

Phenytoin freely pases through the placenta. Human teratogenicity (birth defects) has been reported in women who received phenytoin treatment, and phenytoin has been linked to Fetal Hydantoin Syndrome (FHS). Phenytoin is a teratogen in animals.

Propylene glycol is considered to be relatively non-toxic. It is a mild irritant to the eyes and has been reported to irritate the skin. It may cause skin sensitization resulting in allergic contact dermatitis in susceptible individuals. Inhalation exposure to saturated and supersaturated atmospheres of propylene glycol for prolonged periods of time produced no adverse effects. Propylene glycol may cause nervous system depression, acidosis, stupor, and seizures after chronic ingestion.

INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

NOTE TO PHYSICIAN: In cases of overexposure treat supportively and symtomatically.

SECTION 5. FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

SUITABLE EXTINGUISHING MEDIA:
Carbon dioxide (CO2), extinguishing powder or water spray.

UNSUITABLE EXTINGUISHING MEDIA:
None known.

SPECIAL HAZARDS ARISING FROM THE CHEMICAL

SPECIAL FIRE HAZARDS:
None known.

ADVICE FOR FIREFIGHTERS

SPECIAL FIRE FIGHTING PROCEDURES:
Wear full protective clothing and self-contained breathing apparatus (SCBA).

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

PERSONAL PRECAUTIONS:
Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

SPILL RESPONSE / CLEANUP:
All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7. HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

HANDLING:
Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

CONDITIONS FOR SAFE STORAGE, INCLUDING ANY IMCOMPATIBILITIES

STORAGE:
Store in a cool, dry, well ventilated area.

SPECIFIC END USE(S)
Refer to Section 1 for identified use(s).

See Section 8 for exposure controls and additional safe handling information.

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

The following guidance applies to the handling of the active ingredient(s) in this formulation.

OCCUPATIONAL EXPOSURE BAND (OEB):
Pentobarbital: OEB 4: >=1<10 mcg/m^3. Materials in an OEB 4 category are considered high health hazards. The OEB is range of airborne concentrations expressed as an 8-hour Time Weighted Average (8-hr. TWA) and is intended to be used with Industrial Hygiene Risk Assessment to assist with industrial hygiene sampling and selection of proper controls for worker protection. Consult your site safety and industrial hygiene staff for guidance on handling and control strategies.

Phenytoin Sodium: OEB 3: >=10<100 mcg/m^3. Materials in an OEB 3 category are considered moderate health hazards. The OEB is a range of airborne concentrations expressed as an 8-hour Time Weighted Average (8-hr. TWA) and is intended to be used with Industrial Hygiene Risk Assessment to assist with industrial hygiene sampling and selection of proper controls for worker protection. Consult your site safety and industrial hygiene staff for guidance on handling and control strategies.

OEB/OEL NOTATION(S):
Phenytoin Sodium: This material has a notation of "A" for its ability to cause immediate allergic hypersensitivity reactions or anaphylaxis.

EXPOSURE CONTROLS
The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Respiratory Protection:	Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.

Skin Protection: Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.

Eye Protection: Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.

Body Protection: In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

EXPOSURE LIMIT VALUES

INGREDIENT	CAS NUMBER	ACGIH TLV (TWA)	OSHA PEL (TWA)
Ethyl Alcohol	64-17-5		1000 ppm 1900 mg/m^3

INGREDIENT	CAS NUMBER	ACGIH TLV (STEL / SKIN)	ACGIH TLV (CEIL)	OSHA PEL (STEL / SKIN)	OSHA PEL (CEIL)
Ethyl Alcohol	64-17-5	1000 ppm			

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

FORM: Solution
COLOR: Clear, Pink
ODOR: Odor unknown
ODOR THRESHOLD: Not determined
pH: Not determined
BOILING POINT / RANGE: Not determined
MELTING POINT / RANGE: Not determined
DECOMPOSITION TEMPERATURE: Not determined
VAPOR PRESSURE: Not determined
VAPOR DENSITY: Not determined
SPECIFIC GRAVITY: Not determined
SOLUBILITY:
Water: Not determined
PARTITION COEFFICIENT (log Pow): Not determined
VISCOSITY: Not determined
EVAPORATION RATE: Not determined
FLAMMABILITY DATA:
Flash Point: >=23 C - <=60 C
Flammability (solid, gas): Not determined
UEL: Not determined
LEL: Not determined
Autoignition Temperature: Not determined

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:
Open flames and high temperatures.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
Carbon oxides (COx).

SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below pertains to the following individual ingredients in this formulation, unless indicated otherwise.

LIKELY ROUTES OF EXPOSURE:
Skin, eye, inhalation, and ingestion.

ACUTE TOXICITY DATA

INHALATION:
Propylene glycol caused no adverse effects in monkeys or rats following exposure to saturated atmospheres for prolonged periods of time.

SKIN:
Propylene glycol: Dermal LD50: 20.8 g/kg (rabbit)
Propylene glycol was irritating in a human patch test. Propylene glycol was not irritating to the skin of rabbits, guinea pigs and swine.

EYE:
Propylene glycol was slightly irritating to the eyes of rabbits.

ORAL:
Pentobarbital Sodium: Oral LD50: 118 mg/kg (rat); 65 mg/kg (dog)

Phenytoin Sodium: Oral LD50: 1530 mg/kg (rat); 165-490 mg/kg (mouse)
Toxic doses of phenytoin sodium in animals produce mydriasis, nystagmus, salivation, incoordination, and ataxia. Muscular spasticity, rigidity, tremors, convulsive movements, and opisthotonos has preceded death from respiratory failure.

Propylene glycol: Oral LD50: 21 to 33.7 g/kg (rat), 10 to 20 g/kg (dog)
Propylene glycol caused dyspnea, cramps, loss of equilibrium, depression, analgesia, and death after prolonged moribund state in mice at doses ranging from 23.9 to 31.8 g/kg. In rabbits, 1 to 1.5 g/kg propylene glycol reduced intraocular pressure by raising the osmotic pressure of blood.

DERMAL AND RESPIRATORY SENSITIZATION:
Propylene glycol did not cause sensitization in a human patch test.

ADDITIONAL INFORMATION:
This product is intended for euthansia in dogs upon intravenous administration. Cerebral death in conjunction with respiratory arrest and circulatory collapse is expected.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
Phenytoin effected the peripheral nervous system when given to female rats orally at doses of 300 mg/jg/day for 180 days. Increased thickness of craniofacial bones measured by increases of histomorphometric (osteoblast number, bone mineral apposition rate) and biochemical (skeletal alkaline phosphatase activity, osteocalcin concentrations) parameters of bone formation were observed in rats given phenytoin at doses of 5 mg/kg/day for 36 days by intraperitoneal injection.

Propylene glycol caused no adverse effects in monkeys or rats exposed to saturated vapor concentrations for 12 to 18 months. Rats exposed to 25 or 50% (7.7 and 13.2 g/kg/day) propylene glycol in water died within 69 days in a 140 day study. In a separate study, a diet of 30% propylene glycol was not well tolerated in young rats, and dams could not bring their young to weaning; diets containing 40, 50, or 60% propylene glycol were lethal after a few days.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
Pentobarbital (base) induced a number of anomalies in mice; however, it was not shown to be teratogenic in rats, rabbits, or guinea pigs.

Phenytoin is a teratogen and fetotoxin in rats. It is a teratogen in mice and rabbits, and fetotoxic in monkeys at doses that were also maternally toxic. Phenytoin is not teratogenic in dogs or cats.

Rabbits were administered phenytoin sodium by oral gavage at doses of 150 mg/kg on gestation day 14-16 or 300 mg/kg on gestation days 15-16. Fetuses were examined shortly after the last dose on Day 16. The following effects were observed in the fetuses: digital areas of the limb plates showed edema and dilated blood vessels, vascular disruption occurred with hemorrhages, mesenchymal necrosis, amputation of digits, superficial hemorrhage in the frontal and nasal region, and intracranial and superficial hemorrhage in the central nevous system. Rats were administered phenytoin sodium through intraperitoneal injections at doses of 10, 50, or 100 mg/kg on Day 17 of gestation. There were no adverse effects on pregnancy or neonatal survival in the 10 and 50 mg/kg group. In the 100 mg/kg group, total fetal loss was observed in 50% of the dams, and in the remaining dams, delivery was delayed. In monkeys, oral administration of 60 to 600 mg/kg of phenytoin during gestational days 21 to 50 resulted in dose dependent maternal toxicity, and an increase in embryonic loss. In mice, phenytoin induced cleft palated when administered subcutaneously at doses up to 50 mg/kg from days 9 to 15 of gestation.

Propylene glycol caused decreased food consumption, retarded growth, smaller litters, changes in breeding patterns, and inhibited weaning in rats that were fed 30% propylene glycol through six generations; however, this may have been due to nutritional insufficiency. Propylene glycol was not teratogenic in rabbits, monkeys or chickens.

MUTAGENICITY / GENOTOXICITY:
Pentobarbital (base) was positive in the mouse micronucleus assay, mouse cell DNA inhibition test, hamster cytogenetic assay, and in the hamster dominant lethal test.

Studies with phenytoin showed no induction of micronuclei, chromosomal aberrations, or aneuploidy in human lymphocytes in vivo. There was an increase of polyploidy in one study, and sister chromatid exchange in three of seven studies. Neither chromosomal aberrations nor aneuploidy were induced in human bone marrow. Phenytoin induced mutations in Salmonella typhimurium in the presence of a metabolic activation system in one study, but was negative in Drosophila or mammalian cells in vitro assays in the absence of a metabolic system. Aneuploidy was induced in one study in primary mouse embryonic fibroblasts in vitro. Cell transformation was induced in Syrian hamster embryo. Phenytoin inhibited gap-junctional intercellular communication.

Propylene glycol was negative in a bacterial mutagenicity study (Ames).

CARCINOGENICITY:
This material or product has not been evaluated for carcinogenicity.

IARC has classified phenytoin as a Group 2B (agent is a possible human carcinogen) based on sufficient evidence in animals.

Phenytoin sodium was tested in three strains of mice at oral doses of 60 mg/kg/day for 168 days. There was an increase of thymic lymphomas in two strains of mice, and in the other strain, there was an increase of generatlized lymphomas. In another study, mice administered intraperitoneal injections of 0.6 mg/mouse over 66 days showed an increase in tumors: thymic, mesenteric, and leukemia.

Propylene glycol was not carcinogenic when applied to the skin, or when given orally in mice and rats.

LISTED CARCINOGENS					
INGREDIENT	**CAS NUMBER**	**OSHA**	**IARC**	**NTP**	**ACGIH**
Ethyl Alcohol	64-17-5			K	A3
Phenytoin Sodium	630-93-3		2B		

LISTED CARCINOGEN NOTE:

Phenytoin: IARC has classified phenytoin as a Group 2B (possibly carcinogenic to humans).

Ethanol (ethyl alcohol): IARC (International Agency for Research on Cancer) has classified Alcoholic Beverages as Group 1 (indicating in their evaluation that the agent is carcinogenic to humans). However, occupational handling or manufacturer's specified use of this product is not expected to result in relevant exposures.

SECTION 12. ECOLOGICAL INFORMATION

There are no data for the final product or its formulation(s). The information presented below pertains to the following ingredient(s).

ECOTOXICITY DATA

INGREDIENT ECOTOXICITY

Pentobarbital Sodium: 96-hr LC50 (fathead minnow): 49.5 mg/L

Propylene glycol: 96-hr LC50 (sheepshead minnow): 23,800 mg/L
Propylene glycol: 48-hr EC50 (daphnid): >43,500 mg/L
Propylene glycol: 72-hr EC50 (green algae): >19,000 mg/L

ENVIRONMENTAL DATA

OTHER INGREDIENT ENVIRONMENTAL DATA:

Propylene glycol is expected to be readily biodegradable.

SECTION 13. DISPOSAL CONSIDERATIONS

MATERIAL WASTE:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

SECTION 14. TRANSPORT INFORMATION

Non-regulated per 49 CFR 173.150(f) for ground shipments of non-bulk packagings.

Proper Shipping Name:	Combustible liquid, n.o.s. (ethanol)
Hazard Class:	3
Identification Number:	NA 1993
Packing Group:	III

IATA/ICAO CLASSIFICATION:

Proper Shipping Name:	Ethanol Solutions
Hazard Class:	3
UN Number:	UN 1170
Packing Group:	III

IMDG/IMO CLASSIFICATION:

Proper Shipping Name:	Ethanol Solutions
Hazard Class:	3
UN Number:	UN 1170
Packing Group:	III

SECTION 15. REGULATORY INFORMATION

TSCA LISTING

INGREDIENT	TSCA
Propylene Glycol	X
Ethyl Alcohol	X
Phenytoin Sodium	X
Benzyl Alcohol	X

U.S. STATE REGULATIONS

INGREDIENT	California Proposition 65	CARTK	NJRTK	CTRTK	MARTK
Pentobarbital Sodium	D		3726		
Propylene Glycol			3595		
Ethyl Alcohol	C D	X	0844		X
Phenytoin Sodium	C	X			
Benzyl Alcohol					X

INGREDIENT	PARTK	MNRTK	MIRTK	RIRTK
Propylene Glycol	X	X		X
Ethyl Alcohol	X	X		X
Phenytoin Sodium	X	X		
Benzyl Alcohol	X	X		

SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

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Monday to Friday, 9am to 5pm (US Eastern Time)

MSDS CREATION DATE: 03-Mar-1992

SECTIONS CHANGED (US SUBFORMAT):	14
SIGNIFICANT CHANGES (US SUBFORMAT):	Transportation, OEB

SAFETY DATA SHEET

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.

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

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 plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting. Call a physician or poison control center immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.
Most important symptoms and effects, both acute and delayed	:	Toxic if swallowed. Suspected of causing cancer. Suspected of damaging fertility or the unborn child. Causes damage to organs. Causes damage to organs through prolonged or repeated exposure.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists.
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during fire fighting	:	Do not use a solid water stream as it may scatter and spread fire. Flash back possible over considerable distance. Vapors may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.
Hazardous combustion prod-	:	Carbon oxides

ucts		Nitrogen oxides (NOx) Metal oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Remove all sources of ignition. Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.
Environmental precautions	:	Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Non-sparking tools should be used. Soak up with inert absorbent material. Suppress (knock down) gases/vapors/mists with a water spray jet. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	Use with local exhaust ventilation. Use only in an area equipped with explosion-proof exhaust ventilation if advised by assessment of the local exposure

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 (Form of exposure)	Control parameters / Permissible concentration	Basis
Pentobarbital sodium	57-33-0	TWA	40µg/m3 (OEB3)	Merck
		Wipe limit	400µg/100cm2	Merck
Propylene glycol	57-55-6	TWA	10 mg/m³	US WEEL
Ethanol	64-17-5	TWA	1,000 ppm 1,900 mg/m³	NIOSH REL
		STEL	1,000 ppm	ACGIH
		TWA	1,000 ppm 1,900 mg/m³	OSHA Z-1
Phenytoin sodium	630-93-3	TWA	50 µg/m3 (OEB3)	Merck
		Wipe limit	500 µg/100 cm2	Merck
Benzyl alcohol	100-51-6	TWA	10 ppm	US WEEL

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

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

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)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available

Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Flammable liquid and vapor. Vapors may form explosive mixture with air. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Toxic if swallowed.

Product:

Acute oral toxicity	:	Acute toxicity estimate: 298.5 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: > 200 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method

Ingredients:

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): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rabbit): > 159 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity

Ethanol:

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

Phenytoin sodium:

Acute oral toxicity	:	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

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

Result: negative

Germ cell mutagenicity

Not classified based on available information.

Ingredients:

Propylene glycol:

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

Ethanol:

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

Phenytoin sodium:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative 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 Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Rat Application Route: Intraperitoneal injection

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

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

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

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

		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	:	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)): > 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	:	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:

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 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	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l

		Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 51 mg/l Exposure time: 21 d Method: OECD Test Guideline 211

Persistence and degradability

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

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 1992
Proper shipping name	:	FLAMMABLE LIQUID, TOXIC, N.O.S. (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. (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. (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

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. (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.

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

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

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

US State Regulations

Pennsylvania Right To Know

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

California Prop. 65

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

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

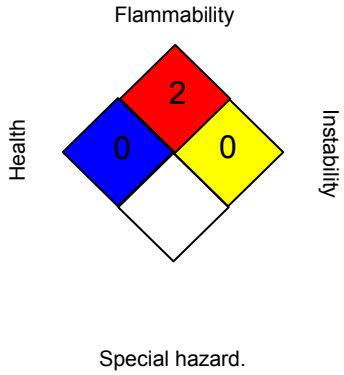
The ingredients of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

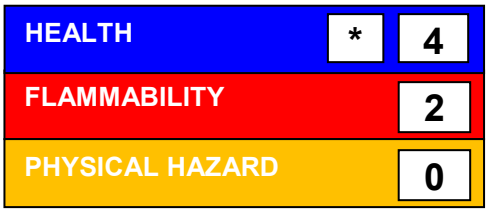
SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS® IV:



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-

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.

US / Z8