

SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures".



Pentobarbital Sodium / Phenytoin Formulation

Version 2.1 Revision Date: 24.04.2019 SDS Number: 2569623-00004 Date of last issue: 18.10.2018
Date of first issue: 27.02.2018

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Pentobarbital Sodium / Phenytoin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet

Company : MSD
Balıkhisar Mah. Köyiçi Küme Evleri No: 765/A
Çubuk Yolu 2. Km
Akyurt / Ankara / TÜRKİYE

Telephone : +90 312 840 53 00

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

National Poison Control Center (UZEM): 114
Emergency: 1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification T.R. SEA No 28848

Flammable liquids, Category 3

H226: Flammable liquid and vapour.

Acute toxicity, Category 3

H301: Toxic if swallowed.

Carcinogenicity, Category 2

H351: Suspected of causing cancer.

Reproductive toxicity, Category 2

H361: Suspected of damaging fertility or the unborn child.

Specific target organ toxicity - single exposure, Category 1

H370: Causes damage to organs.

Specific target organ toxicity - repeated exposure, Category 2

H373: May cause damage to organs through prolonged or repeated exposure.

Long-term (chronic) aquatic hazard, Category 3

H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling T.R. SEA No 28848

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Signal word :

Danger

Hazard statements :

H226 Flammable liquid and vapour.
H301 Toxic if swallowed.
H351 Suspected of causing cancer.
H361 Suspected of damaging fertility or the unborn child.
H370 Causes damage to organs.
H373 May cause damage to organs through prolonged or repeated exposure.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements :

Prevention:
P201 Obtain special instructions before use.
P210 Keep away from heat/sparks/open flames/hot surfaces.
No smoking.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician. Rinse mouth.
P307 + P311 IF exposed: Call a POISON CENTER or doctor/ physician.

Hazardous components which must be listed on the label:

Pentobarbital sodium

Phenytoin sodium

Benzyl alcohol

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 5 %

2.3 Other hazards

Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration num- ber | Classification | Concentration (% w/w) |
|---------------|--|----------------|--------------------------|
| | | | |

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| | | | |
|----------------------|---------------------------------------|---|--------------|
| Pentobarbital sodium | 57-33-0 200-323-9 | Acute Tox.3; H301 Repr.2; H361d STOT SE1; H370 Aquatic Chronic3; H412 | >= 30 - < 50 |
| Ethanol | 64-17-5 200-578-6 603-002-00-5 | Flam. Liq.2; H225 Eye Irrit.2; H319 | >= 10 - < 20 |
| Phenytoin sodium | 630-93-3 211-148-2 | Acute Tox.4; H302 Carc.2; H351 Repr.2; H361 STOT RE1; H372 | >= 3 - < 10 |
| Benzyl alcohol | 100-51-6 202-859-9 603-057-00-5 | Acute Tox.4; H302 Acute Tox.4; H332 Eye Irrit.2; H319 | >= 1 - < 10 |

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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.

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 centre immediately.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Toxic if swallowed.
Suspected of causing cancer.
Suspected of damaging fertility or the unborn child.

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

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Remove all sources of ignition.
Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

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6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

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

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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 vapour 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.

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Hygiene measures : Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : 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.

Advice on common storage : 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

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|----------------------|----------|-------------------------------|--------------------|----------|
| Pentobarbital sodium | 57-33-0 | TWA | 40µg/m3 (OEB3) | Internal |
| | | Wipe limit | 400µg/100cm2 | Internal |
| Phenytoin sodium | 630-93-3 | TWA | 50 µg/m3 (OEB3) | Internal |
| | | Wipe limit | 500 µg/100 cm2 | Internal |

Derived No Effect Level (DNEL) :

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|----------------|---------|-----------------|--------------------------|-------|
| | | | | |

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| | | | | |
|------------------|-----------|--------------|----------------------------|------------------|
| Propylene glycol | Workers | Inhalation | Long-term local effects | 10 mg/m3 |
| | Workers | Inhalation | Long-term systemic effects | 168 mg/m3 |
| | Consumers | Inhalation | Long-term local effects | 10 mg/m3 |
| | Consumers | Inhalation | Long-term systemic effects | 50 mg/m3 |
| Ethanol | Workers | Inhalation | Acute local effects | 1900 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 343 mg/kg bw/day |
| | Workers | Inhalation | Long-term systemic effects | 950 mg/m3 |
| | Consumers | Inhalation | Acute local effects | 950 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 206 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 114 mg/m3 |
| | Consumers | Ingestion | Long-term systemic effects | 87 mg/kg bw/day |
| Benzyl alcohol | Workers | Inhalation | Long-term systemic effects | 22 mg/m3 |
| | Workers | Inhalation | Acute systemic effects | 110 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 8 mg/kg bw/day |
| | Workers | Skin contact | Acute systemic effects | 40 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 5,4 mg/m3 |
| | Consumers | Inhalation | Acute systemic effects | 27 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 4 mg/kg bw/day |
| | Consumers | Skin contact | Acute systemic effects | 20 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 4 mg/kg bw/day |
| | Consumers | Ingestion | Acute systemic effects | 20 mg/kg bw/day |

Predicted No Effect Concentration (PNEC) :

| Substance name | Environmental Compartment | Value |
|------------------|---------------------------|------------|
| Propylene glycol | Fresh water | 260 mg/l |
| | Marine water | 26 mg/l |
| | Intermittent use/release | 183 mg/l |
| | Sewage treatment plant | 20000 mg/l |
| | Fresh water sediment | 572 mg/kg |
| | Marine sediment | 57,2 mg/kg |
| | Soil | 50 mg/kg |
| Ethanol | Fresh water | 0,96 mg/l |

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|----------------|----------------------------|----------------|
| | Marine water | 0,79 mg/l |
| | Intermittent use/release | 2,75 mg/l |
| | Sewage treatment plant | 580 mg/l |
| | Fresh water sediment | 3,6 mg/kg |
| | Marine sediment | 2,9 mg/kg |
| | Soil | 0,63 mg/kg |
| | Oral (Secondary Poisoning) | 720 mg/kg food |
| Benzyl alcohol | Fresh water | 1 mg/l |
| | Marine water | 0,1 mg/l |
| | Intermittent use/release | 2,3 mg/l |
| | Sewage treatment plant | 39 mg/l |
| | Fresh water sediment | 5,27 mg/kg |
| | Marine sediment | 0,527 mg/kg |
| | Soil | 0,456 mg/kg |

8.2 Exposure controls

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

| | |
|--------------------------|--|
| 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. |
| 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. |
| 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. |
| Respiratory protection | : Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines. |
| Filter type | : Combined particulates and organic vapour type (A-P) |

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SECTION 9: Physical and chemical properties

9.1 Information on basic 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 |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | No data available |
| Relative vapour density | : | No data available |
| Relative density | : | No data available |
| Density | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | 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. |

9.2 Other information

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| | | |
|------------------------|---|-------------------|
| Flammability (liquids) | : | Not applicable |
| Molecular weight | : | No data available |
| Particle size | : | No data available |

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Flammable liquid and vapour.
Vapours may form explosive mixture with air.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

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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

Ethanol:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg
Method: OECD Test Guideline 401
Acute inhalation toxicity : LC50 (Rat): 124,7 mg/l
Exposure time: 4 h
Test atmosphere: vapour

Phenytoin sodium:

Acute oral toxicity : 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.

Components:

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.

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Components:

Ethanol:

| | | |
|---------|---|--|
| Species | : | Rabbit |
| Method | : | OECD Test Guideline 405 |
| Result | : | Irritation to eyes, reversing within 21 days |

Benzyl alcohol:

| | | |
|---------|---|--|
| Species | : | Rabbit |
| Method | : | OECD Test Guideline 405 |
| Result | : | Irritation to eyes, reversing within 21 days |

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Ethanol:

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

Benzyl alcohol:

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

Germ cell mutagenicity

Not classified based on available information.

Components:

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 |
|----------------------|---|--|

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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

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Carcinogenicity

Suspected of causing cancer.

Components:

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 |

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. |
|------------------------------------|---|---|

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 foetal development | : | Test Type: Embryo-foetal development Species: Rabbit |

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Application Route: Ingestion
Developmental Toxicity: LOAEL: 150 mg/kg body weight
Result: positive

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

STOT - single exposure

Causes damage to organs.

Components:

Pentobarbital sodium:

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

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Phenytoin sodium:

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

Repeated dose toxicity

Components:

Ethanol:

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According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures".



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| | | |
|-------------------|---|-------------|
| 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

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

12.1 Toxicity

Product:

Components:

Pentobarbital sodium:

| | | |
|------------------|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): 49,5 mg/l Exposure time: 96 h |
|------------------|---|---|

Ethanol:

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According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures".



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| | | |
|--|---|--|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): > 1.000 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Ceriodaphnia (water flea)): > 1.000 mg/l Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l Exposure time: 72 h EC10 (Chlorella vulgaris (Fresh water algae)): 11,5 mg/l Exposure time: 72 h |
| Toxicity to microorganisms | : | EC50 (Pseudomonas putida): 6.500 mg/l Exposure time: 16 h |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 9,6 mg/l Exposure time: 9 d Species: Daphnia magna (Water flea) |

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/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: 51 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211 |

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12.2 Persistence and degradability

Components:

Ethanol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 84 %
Exposure time: 20 d

Benzyl alcohol:

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

12.3 Bioaccumulative potential

Components:

Ethanol:

Partition coefficient: n-octanol/water : log Pow: -0,35

Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1,05

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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.

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SECTION 14: Transport information

14.1 UN number

| | | |
|-------------|---|---------|
| ADN | : | UN 1993 |
| ADR | : | UN 1993 |
| RID | : | UN 1993 |
| IMDG | : | UN 1993 |
| IATA | : | UN 1993 |

14.2 UN proper shipping name

| | | |
|-------------|---|---|
| ADN | : | FLAMMABLE LIQUID, N.O.S. (Ethanol, Pentobarbital sodium) |
| ADR | : | FLAMMABLE LIQUID, N.O.S. (Ethanol, Pentobarbital sodium) |
| RID | : | FLAMMABLE LIQUID, N.O.S. (Ethanol, Pentobarbital sodium) |
| IMDG | : | FLAMMABLE LIQUID, N.O.S. (Ethanol, Pentobarbital sodium) |
| IATA | : | Flammable liquid, n.o.s. (Ethanol, Pentobarbital sodium) |

14.3 Transport hazard class(es)

| | | |
|-------------|---|---|
| ADN | : | 3 |
| ADR | : | 3 |
| RID | : | 3 |
| IMDG | : | 3 |
| IATA | : | 3 |

14.4 Packing group

| | | |
|------------------------------|---|-------|
| ADN | | |
| Packing group | : | III |
| Classification Code | : | F1 |
| Hazard Identification Number | : | 30 |
| Labels | : | 3 |
| ADR | | |
| Packing group | : | III |
| Classification Code | : | F1 |
| Hazard Identification Number | : | 30 |
| Labels | : | 3 |
| Tunnel restriction code | : | (D/E) |
| RID | | |
| Packing group | : | III |

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According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures".



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Classification Code : F1
Hazard Identification Number : 30
Labels : 3

IMDG

Packing group : III
Labels : 3
EmS Code : F-E, S-E

IATA (Cargo)

Packing instruction (cargo aircraft) : 366
Packing instruction (LQ) : Y344
Packing group : III
Labels : Flammable Liquids

IATA (Passenger)

Packing instruction (passenger aircraft) : 355
Packing instruction (LQ) : Y344
Packing group : III
Labels : Flammable Liquids

14.5 Environmental hazards

ADN

Environmentally hazardous : no

ADR

Environmentally hazardous : no

RID

Environmentally hazardous : no

IMDG

Marine pollutant : no

14.6 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.

14.7 Transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17) : Conditions of restriction for the following entries should be considered: Number on list 3

Other regulations:

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regu-

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According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures".



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lation on Safety data sheets regarding hazardous substances and mixtures".
Regulation on Classification, Labelling and Packaging of Substances and Mixtures. Dated 11 December 2013, Numbered 28848 (Bis) Ministry of Environment and Forestry.
Regulation on Health and Safety Measures Of Working with Chemicals Substances Dated 12.08.13, numbered 28733 Ministry of Labour and Social Security.

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

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

SECTION 16: Other information

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

Full text of H-Statements

| | |
|-------|---|
| H225 | : Highly flammable liquid and vapour. |
| H301 | : Toxic if swallowed. |
| H302 | : Harmful if swallowed. |
| H319 | : Causes serious eye irritation. |
| H332 | : Harmful if inhaled. |
| H351 | : Suspected of causing cancer. |
| H361 | : Suspected of damaging fertility or the unborn child. |
| H361d | : Suspected of damaging the unborn child. |
| H370 | : Causes damage to organs. |
| H372 | : Causes damage to organs through prolonged or repeated exposure. |
| H412 | : Harmful to aquatic life with long lasting effects. |

Full text of other abbreviations

| | |
|-----------------|--|
| Acute Tox. | : Acute toxicity |
| Aquatic Chronic | : Long-term (chronic) aquatic hazard |
| Carc. | : Carcinogenicity |
| Eye Irrit. | : Eye irritation |
| Flam. Liq. | : Flammable liquids |
| Repr. | : Reproductive toxicity |
| STOT RE | : Specific target organ toxicity - repeated exposure |
| STOT SE | : Specific target organ toxicity - single exposure |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response;

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EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; 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; 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; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; 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

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/>

Classification of the mixture:

| | |
|-------------------|------|
| Flam. Liq. 3 | H226 |
| Acute Tox. 3 | H301 |
| Carc. 2 | H351 |
| Repr. 2 | H361 |
| STOT SE 1 | H370 |
| STOT RE 2 | H373 |
| Aquatic Chronic 3 | H412 |

Classification procedure:

| |
|-------------------------------------|
| Based on product data or assessment |
| Calculation method |

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

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 mate-

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TR / EN