

## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 30.09.2023  |
| 7.0     | 28.09.2024     | 673761-00022 | Date of first issue: 12.05.2016 |

---

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Pentobarbital Sodium / Phenytoin Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road  
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

---

### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

##### Classification

Toxic, Highly flammable liquids

##### GHS Classification

Flammable liquids : Category 3

Acute toxicity (Oral) : Category 3

Skin sensitisation : Category 1

Carcinogenicity (Oral) : Category 2

Reproductive toxicity : Category 2

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

Specific target organ toxicity - : Category 2 (Central nervous system)  
repeated exposure

Short-term (acute) aquatic : Category 3  
hazard

Long-term (chronic) aquatic : Category 3  
hazard

## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 30.09.2023  |
| 7.0     | 28.09.2024     | 673761-00022 | Date of first issue: 12.05.2016 |

### GHS label elements

|                          |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|--------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hazard pictograms        | : |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Signal word              | : | Danger                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Hazard statements        | : | H226 Flammable liquid and vapour.<br>H301 Toxic if swallowed.<br>H317 May cause an allergic skin reaction.<br>H351 Suspected of causing cancer if swallowed.<br>H361 Suspected of damaging fertility or the unborn child.<br>H370 Causes damage to organs (Central nervous system).<br>H373 May cause damage to organs (Central nervous system) through prolonged or repeated exposure.<br>H412 Harmful to aquatic life with long lasting effects.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Precautionary statements | : | <b>Prevention:</b><br>P203 Obtain, read and follow all safety instructions before use.<br>P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.<br>P260 Do not breathe mist or vapours.<br>P264 Wash hands thoroughly after handling.<br>P270 Do not eat, drink or smoke when using this product.<br>P272 Contaminated work clothing should not be allowed out of the workplace.<br>P273 Avoid release to the environment.<br>P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.<br><br><b>Response:</b><br>P301 + P316 + P330 IF SWALLOWED: Get emergency medical help immediately. Rinse mouth.<br>P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse affected areas with water.<br>P308 + P316 IF exposed or concerned: Get emergency medical help immediately.<br>P333 + P317 If skin irritation or rash occurs: Get medical help.<br>P362 + P364 Take off contaminated clothing and wash it before reuse.<br><br><b>Storage:</b><br>P405 Store locked up.<br><br><b>Disposal:</b><br>P501 Dispose of contents/ container to an approved waste disposal plant. |

### Other hazards which do not result in classification

Vapours may form explosive mixture with air.

## Pentobarbital Sodium / Phenytoin Formulation

Version 7.0      Revision Date: 28.09.2024      SDS Number: 673761-00022      Date of last issue: 30.09.2023  
Date of first issue: 12.05.2016

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

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

#: Voluntarily-disclosed substance

### 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Call a physician or poison control centre immediately.  
Rinse mouth thoroughly with water.  
Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : Toxic if swallowed.  
May cause an allergic skin reaction.  
Suspected of causing cancer if swallowed.  
Suspected of damaging fertility or the unborn child.  
Causes damage to organs.  
May cause damage to organs through prolonged or repeated exposure.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

### 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : High volume water jet

## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 30.09.2023  |
| 7.0     | 28.09.2024     | 673761-00022 | Date of first issue: 12.05.2016 |

---

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

### 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Remove all sources of ignition.  
Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Non-sparking tools should be used.  
Soak up with inert absorbent material.  
Suppress (knock down) gases/vapours/mists with a water spray jet.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

## Pentobarbital Sodium / Phenytoin Formulation

Version: 7.0      Revision Date: 28.09.2024      SDS Number: 673761-00022      Date of last issue: 30.09.2023  
Date of first issue: 12.05.2016

### 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.  
Use explosion-proof electrical, ventilating and lighting equipment.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe mist or vapours.  
Do not swallow.  
Avoid contact with eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Non-sparking tools should be used.  
Keep container tightly closed.  
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
Take precautionary measures against static discharges.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labelled containers.  
Store locked up.  
Keep tightly closed.  
Keep in a cool, well-ventilated place.  
Store in accordance with the particular national regulations.  
Keep away from heat and sources of ignition.
- Materials to avoid : Do not store with the following product types:  
Self-reactive substances and mixtures  
Organic peroxides  
Oxidizing agents  
Flammable gases  
Pyrophoric liquids  
Pyrophoric solids  
Self-heating substances and mixtures  
Poisonous gases  
Explosives

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

| Components           | CAS-No. | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | Basis    |
|----------------------|---------|----------------------------------|------------------------------------------------|----------|
| Pentobarbital sodium | 57-33-0 | TWA                              | 40µg/m <sup>3</sup> (OEB3)                     | Internal |
|                      |         | Wipe limit                       | 400µg/100cm <sup>2</sup>                       | Internal |
| Ethanol              | 64-17-5 | TWA                              | 1,000 ppm<br>1,900 mg/m <sup>3</sup>           | IN OEL   |
|                      |         | STEL                             | 1,000 ppm                                      | ACGIH    |

## Pentobarbital Sodium / Phenytoin Formulation

Version 7.0      Revision Date: 28.09.2024      SDS Number: 673761-00022      Date of last issue: 30.09.2023  
Date of first issue: 12.05.2016

|                  |          |            |                 |          |
|------------------|----------|------------|-----------------|----------|
| Phenytoin sodium | 630-93-3 | TWA        | 50 µg/m3 (OEB3) | Internal |
|                  |          | Wipe limit | 500 µg/100 cm2  | Internal |

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

### Personal protective equipment

**Respiratory protection** : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

**Filter type** : Combined particulates and organic vapour type

**Hand protection**

**Material** : Chemical-resistant gloves

**Remarks** : Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.

**Eye protection** : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection** : Work uniform or laboratory coat.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.

**Hygiene measures** : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Contaminated work clothing should not be allowed out of the workplace.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 30.09.2023  |
| 7.0     | 28.09.2024     | 673761-00022 | Date of first issue: 12.05.2016 |

---

|                                                  |   |                                                          |
|--------------------------------------------------|---|----------------------------------------------------------|
| Appearance                                       | : | liquid                                                   |
| Colour                                           | : | pink                                                     |
| Odour                                            | : | No data available                                        |
| Odour Threshold                                  | : | No data available                                        |
| pH                                               | : | No data available                                        |
| Melting point/freezing point                     | : | No data available                                        |
| Initial boiling point and boiling range          | : | No data available                                        |
| Flash point                                      | : | 44 - 60 °C                                               |
| Evaporation rate                                 | : | No data available                                        |
| Flammability (solid, gas)                        | : | Not applicable                                           |
| Flammability (liquids)                           | : | Not applicable                                           |
| Upper explosion limit / Upper flammability limit | : | No data available                                        |
| Lower explosion limit / Lower flammability limit | : | No data available                                        |
| 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. |

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 30.09.2023  |
| 7.0     | 28.09.2024     | 673761-00022 | Date of first issue: 12.05.2016 |

Molecular weight : No data available

Particle characteristics  
Particle size : No data available

### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.  
Chemical stability : Stable under normal conditions.  
Possibility of hazardous reactions : Flammable liquid and vapour.  
Vapours may form explosive mixture with air.  
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

### 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: 261.66 mg/kg  
Method: Calculation method

#### Components:

##### **Pentobarbital sodium:**

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

##### **Ethanol:**

Acute oral toxicity : LD50 (Rat): 10,470 mg/kg  
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat, male): 116.9 mg/l  
Exposure time: 4 h  
Test atmosphere: vapour

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

## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 30.09.2023  |
| 7.0     | 28.09.2024     | 673761-00022 | Date of first issue: 12.05.2016 |

**II**

### Phenytoin sodium:

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

### Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 5.4 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: The substance or mixture has no acute inhalation toxicity

### 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.

### 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

May cause an allergic skin reaction.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 30.09.2023  |
| 7.0     | 28.09.2024     | 673761-00022 | Date of first issue: 12.05.2016 |

### Respiratory sensitisation

Not classified based on available information.

### Components:

#### Ethanol:

|                 |                                  |
|-----------------|----------------------------------|
| Test Type       | : Mouse ear swelling test (MEST) |
| Exposure routes | : Skin contact                   |
| Species         | : Mouse                          |
| Result          | : negative                       |

#### Phenytoin sodium:

|            |                                                           |
|------------|-----------------------------------------------------------|
| Assessment | : Probability or evidence of skin sensitisation in humans |
|------------|-----------------------------------------------------------|

#### Benzyl alcohol:

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

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

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Ethanol:

|                       |                                                                                                                                                      |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Method: OECD Test Guideline 471<br>Result: negative                                          |
|                       | : Test Type: In vitro mammalian cell gene mutation test<br>Method: OECD Test Guideline 476<br>Result: negative                                       |
|                       | : Test Type: Chromosome aberration test in vitro<br>Result: negative                                                                                 |
| Genotoxicity in vivo  | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

#### Phenytoin sodium:

|                       |                                                                                                                           |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br>Remarks: Based on data from similar materials |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------|

## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 30.09.2023  |
| 7.0     | 28.09.2024     | 673761-00022 | Date of first issue: 12.05.2016 |

|                      |                                                                                                                                                                                                            |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                      | 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 mam-<br>malian cells                                                                                                                                |
|                      | Result: positive                                                                                                                                                                                           |
|                      | Remarks: Based on data from similar materials                                                                                                                                                              |
| Genotoxicity in vivo | : Test Type: Mammalian erythrocyte micronucleus test (in vivo<br>cytogenetic assay)<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative<br>Remarks: Based on data from similar materials |

### **Benzyl alcohol:**

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

### **Carcinogenicity**

Suspected of causing cancer if swallowed.

### **Components:**

#### **Phenytoin sodium:**

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

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

|                                   |                                                                |
|-----------------------------------|----------------------------------------------------------------|
| Carcinogenicity - Assess-<br>ment | : Limited evidence of carcinogenicity in animal studies (oral) |
|-----------------------------------|----------------------------------------------------------------|

#### **Benzyl alcohol:**

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

## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 30.09.2023  |
| 7.0     | 28.09.2024     | 673761-00022 | Date of first issue: 12.05.2016 |

### 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<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |
|----------------------|---|-----------------------------------------------------------------------------------------------------------------------------|

#### Phenytoin sodium:

|                                    |   |                                                                                                                                                                               |
|------------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility               | : | Test Type: reproductive and developmental toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: positive<br>Remarks: Based on data from similar materials |
| Effects on foetal development      | : | Test Type: reproductive and developmental toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: positive<br>Remarks: Based on data from similar materials |
| Reproductive toxicity - Assessment | : | Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.                                                        |

#### Benzyl alcohol:

|                               |   |                                                                                                                                                                       |
|-------------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility          | : | Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative<br>Remarks: Based on data from similar materials |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative                                                            |

### STOT - single exposure

Causes damage to organs (Central nervous system).

### Components:

#### Pentobarbital sodium:

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

## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 30.09.2023  |
| 7.0     | 28.09.2024     | 673761-00022 | Date of first issue: 12.05.2016 |

### STOT - repeated exposure

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

#### Components:

##### Phenytoin sodium:

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

### Repeated dose toxicity

#### Components:

##### Ethanol:

|                   |               |
|-------------------|---------------|
| Species           | : Rat         |
| NOAEL             | : 1,730 mg/kg |
| LOAEL             | : 3,200 mg/kg |
| Application Route | : Ingestion   |
| Exposure time     | : 90 Days     |

##### Phenytoin sodium:

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

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

##### Benzyl alcohol:

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

### Aspiration toxicity

Not classified based on available information.

## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 30.09.2023  |
| 7.0     | 28.09.2024     | 673761-00022 | Date of first issue: 12.05.2016 |

### 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

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

##### **Pentobarbital sodium:**

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

##### **Ethanol:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 14,200 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 5,012 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l  
Exposure time: 72 h

EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l  
Exposure time: 72 h

Toxicity to microorganisms : EC50 (Protozoa): 5,800 mg/l  
Exposure time: 4 h

Toxicity to fish (Chronic toxicity) : NOEC:  $\geq 79$  mg/l  
Exposure time: 100 d  
Species: Oryzias latipes (Japanese medaka)

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:**

Toxicity to fish : EC50 (Danio rerio (zebra fish)):  $> 10 - 100$  mg/l  
Exposure time: 72 h  
Remarks: Based on data from similar materials

Toxicity to daphnia and other : Remarks: No toxicity at the limit of solubility

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 30.09.2023  |
| 7.0     | 28.09.2024     | 673761-00022 | Date of first issue: 12.05.2016 |

aquatic invertebrates

### Benzyl alcohol:

|                                                                        |                                                                                                                                                                                                                                                              |
|------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish                                                       | : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l<br>Exposure time: 96 h                                                                                                                                                                               |
| Toxicity to daphnia and other aquatic invertebrates                    | : EC50 (Daphnia magna (Water flea)): 230 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202                                                                                                                                                      |
| Toxicity to algae/aquatic plants                                       | : EC50 ( Pseudokirchneriella subcapitata (green algae)): 770 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC ( Pseudokirchneriella subcapitata (green algae)): 310 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC: 51 mg/l<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea)<br>Method: OECD Test Guideline 211                                                                                                                                             |

### Persistence and degradability

#### Components:

##### Ethanol:

|                  |                                                                                 |
|------------------|---------------------------------------------------------------------------------|
| Biodegradability | : Result: Readily biodegradable.<br>Biodegradation: 84 %<br>Exposure time: 20 d |
|------------------|---------------------------------------------------------------------------------|

##### Phenytoin sodium:

|                  |                                                                                                                           |
|------------------|---------------------------------------------------------------------------------------------------------------------------|
| Biodegradability | : Result: Not readily biodegradable.<br>Method: OECD Test Guideline 301C<br>Remarks: Based on data from similar materials |
|------------------|---------------------------------------------------------------------------------------------------------------------------|

##### Benzyl alcohol:

|                  |                                                                                      |
|------------------|--------------------------------------------------------------------------------------|
| Biodegradability | : Result: Readily biodegradable.<br>Biodegradation: 92 - 96 %<br>Exposure time: 14 d |
|------------------|--------------------------------------------------------------------------------------|

### Bioaccumulative potential

#### Components:

##### Ethanol:

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

## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 30.09.2023  |
| 7.0     | 28.09.2024     | 673761-00022 | Date of first issue: 12.05.2016 |

### II

#### Phenytoin sodium:

|                                        |   |                      |
|----------------------------------------|---|----------------------|
| Partition coefficient: n-octanol/water | : | log Pow: 2.84        |
|                                        | : | Remarks: Calculation |

#### Benzyl alcohol:

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

#### Mobility in soil

No data available

#### Other adverse effects

No data available

## 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

|                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                    |
|------------------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Waste from residues    | : | Do not dispose of waste into sewer.<br>Dispose of in accordance with local regulations.                                                                                                                                                                                                                                                                                                                            |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>Empty containers retain residue and can be dangerous.<br>Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death.<br>If not otherwise specified: Dispose of as unused product. |

## 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

|                           |   |                                                             |
|---------------------------|---|-------------------------------------------------------------|
| UN number                 | : | UN 1993                                                     |
| Proper shipping name      | : | FLAMMABLE LIQUID, N.O.S.<br>(Ethanol, Pentobarbital sodium) |
| Class                     | : | 3                                                           |
| Packing group             | : | III                                                         |
| Labels                    | : | 3                                                           |
| Environmentally hazardous | : | no                                                          |

##### IATA-DGR

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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 30.09.2023  |
| 7.0     | 28.09.2024     | 673761-00022 | Date of first issue: 12.05.2016 |

### IMDG-Code

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

### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

### 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.

## 15. REGULATORY INFORMATION

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

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

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

## 16. OTHER INFORMATION

|               |   |            |
|---------------|---|------------|
| Revision Date | : | 28.09.2024 |
|---------------|---|------------|

### Further information

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

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

|             |   |            |
|-------------|---|------------|
| Date format | : | dd.mm.yyyy |
|-------------|---|------------|

### Full text of other abbreviations

|        |   |                                                                               |
|--------|---|-------------------------------------------------------------------------------|
| ACGIH  | : | USA. ACGIH Threshold Limit Values (TLV)                                       |
| IN OEL | : | India. Permissible levels of certain chemical substances in work environment. |

|              |   |                                                    |
|--------------|---|----------------------------------------------------|
| ACGIH / STEL | : | Short-term exposure limit                          |
| IN OEL / TWA | : | Time-Weighted Average Concentration (TWA) (8 hrs.) |

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 30.09.2023  |
| 7.0     | 28.09.2024     | 673761-00022 | Date of first issue: 12.05.2016 |

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

IN / EN