

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 28.09.2024  |
| 8.1     | 14.04.2025     | 673764-00024 | Date of first issue: 12.05.2016 |

### 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 Sub-  
stance/Mixture : Veterinary product

Recommended restrictions  
on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Kilsheelan  
Clonmel Tipperary, IE

Telephone : 353-51-601000

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

#### 1.4 Emergency telephone number

+1-908-423-6000

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

|                                                                |                                                                          |
|----------------------------------------------------------------|--------------------------------------------------------------------------|
| Flammable liquids, Category 3                                  | H226: Flammable liquid and vapour.                                       |
| Acute toxicity, Category 3                                     | H301: Toxic if swallowed.                                                |
| Skin sensitisation, Category 1                                 | H317: May cause an allergic skin reaction.                               |
| Carcinogenicity, Category 2                                    | H351: Suspected of causing cancer if swallowed.                          |
| 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 (REGULATION (EC) No 1272/2008)

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Hazard pictograms :



Signal word : Danger

Hazard statements :

- H226 Flammable liquid and vapour.
- H301 Toxic if swallowed.
- H317 May cause an allergic skin reaction.
- H351 Suspected of causing cancer if swallowed.
- H361 Suspected of damaging fertility or the unborn child.
- H370 Causes damage to organs.
- 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, hot surfaces, sparks, open flames and other ignition sources. 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/ doctor. Rinse mouth.  
P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.

Hazardous components which must be listed on the label:

Pentobarbital sodium  
Phenytoin sodium  
Benzyl alcohol

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Vapours may form explosive mixture with air.

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### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

##### Components

| Chemical name        | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification                                                                                                                                                                                            | Concentration<br>(% w/w) |
|----------------------|-------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Pentobarbital sodium | 57-33-0<br>200-323-9                                  | Acute Tox. 3; H301<br>Repr. 2; H361d<br>STOT SE 1; H370<br>(Central nervous<br>system)<br>Aquatic Chronic 3;<br>H412<br><br>Acute toxicity esti-<br>mate<br><br>Acute oral toxicity:<br>118 mg/kg         | >= 30 - < 50             |
| Ethanol#             | 64-17-5<br>200-578-6<br>603-002-00-5                  | Flam. Liq. 2; H225<br>Eye Irrit. 2; H319<br><br>specific concentra-<br>tion limit<br>Eye Irrit. 2; H319<br>>= 50 %                                                                                        | >= 10 - < 20             |
| Phenytoin sodium     | 630-93-3<br>211-148-2                                 | Acute Tox. 3; H301<br>Skin Sens. 1; H317<br>Carc. 2; H351<br>Repr. 2; H361<br>STOT RE 1; H372<br>(Central nervous<br>system)<br><br>Acute toxicity esti-<br>mate<br><br>Acute oral toxicity:<br>100 mg/kg | >= 3 - < 10              |
| Benzyl alcohol       | 100-51-6<br>202-859-9<br>603-057-00-5                 | Acute Tox. 4; H302<br>Eye Irrit. 2; H319<br>Skin Sens. 1B;<br>H317<br><br>Acute toxicity esti-<br>mate<br><br>Acute oral toxicity:                                                                        | >= 1 - < 10              |

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|  |  |             |  |
|--|--|-------------|--|
|  |  | 1.200 mg/kg |  |
|--|--|-------------|--|

For explanation of abbreviations see section 16.  
#: Voluntarily-disclosed substance

### 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.<br>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 (see section 8).                                           |
| If inhaled                 | : | If inhaled, remove to fresh air.<br>Get medical attention.                                                                                                                                                            |
| In case of skin contact    | : | In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact     | : | Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists.                                                                                                                  |
| If swallowed               | : | If swallowed, DO NOT induce vomiting.<br>Call a physician or poison control centre immediately.<br>Rinse mouth thoroughly with water.<br>Never give anything by mouth to an unconscious person.                       |

#### 4.2 Most important symptoms and effects, both acute and delayed

- |       |   |                                                                                                                                                                                                                                                                    |
|-------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Risks | : | Toxic if swallowed.<br>May cause an allergic skin reaction.<br>Suspected of causing cancer if swallowed.<br>Suspected of damaging fertility or the unborn child.<br>Causes damage to organs.<br>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. |
|-----------|---|-----------------------------------------|

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### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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<sub>x</sub>)  
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 (see section 7) and personal protective equipment recommendations (see section 8).

#### 6.2 Environmental precautions

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.

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### 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.

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## 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 | : | If sufficient ventilation is unavailable, use with local exhaust ventilation.<br>Use explosion-proof electrical, ventilating and lighting equipment.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Advice on safe handling | : | Do not get on skin or clothing.<br>Do not breathe mist or vapours.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Non-sparking tools should be used.<br>Keep container tightly closed.<br>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures        | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace.<br>Wash contaminated clothing before re-use.                                                                                                                                                                                                                                                                                                                                                                            |

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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  
Self-reactive substances and mixtures  
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  
Very acutely toxic substances and mixtures

### 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/m <sup>3</sup> (OEB3)       | Internal            |
|                      |          | Wipe limit                    | 400µg/100cm <sup>2</sup>         | Internal            |
| Propylene glycol     | 57-55-6  | TWA                           | 25 ppm<br>79 mg/m <sup>3</sup>   | FOR-2011-12-06-1358 |
| Ethanol              | 64-17-5  | TWA                           | 500 ppm<br>950 mg/m <sup>3</sup> | FOR-2011-12-06-1358 |
| Phenytoin sodium     | 630-93-3 | TWA                           | 50 µg/m <sup>3</sup> (OEB3)      | Internal            |
|                      |          | Wipe limit                    | 500 µg/100 cm <sup>2</sup>       | Internal            |

#### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

| Substance name   | End Use | Exposure routes | Potential health effects | Value                |
|------------------|---------|-----------------|--------------------------|----------------------|
| Propylene glycol | Workers | Inhalation      | Long-term local ef-      | 10 mg/m <sup>3</sup> |

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|                |           |              |                            |                  |
|----------------|-----------|--------------|----------------------------|------------------|
|                |           |              | fects                      |                  |
|                | 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   | Long-term systemic effects | 380 mg/m3        |
|                | Workers   | Skin contact | Long-term systemic effects | 267 mg/kg bw/day |
|                | Consumers | Inhalation   | Long-term systemic effects | 114 mg/m3        |
| 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) according to Regulation (EC) No. 1907/2006

| Substance name   | Environmental Compartment | Value                        |
|------------------|---------------------------|------------------------------|
| Propylene glycol | Fresh water               | 260 mg/l                     |
|                  | Freshwater - intermittent | 183 mg/l                     |
|                  | Marine water              | 26 mg/l                      |
|                  | Sewage treatment plant    | 20000 mg/l                   |
|                  | Fresh water sediment      | 572 mg/kg dry weight (d.w.)  |
|                  | Marine sediment           | 57,2 mg/kg dry weight (d.w.) |
|                  | Soil                      | 50 mg/kg dry weight (d.w.)   |
| Ethanol          | Fresh water               | 0,96 mg/l                    |
|                  | Freshwater - intermittent | 2,75 mg/l                    |
|                  | Marine water              | 0,79 mg/l                    |
|                  | Sewage treatment plant    | 580 mg/l                     |
|                  | Fresh water sediment      | 3,6 mg/kg dry weight (d.w.)  |



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|                |                            |                              |
|----------------|----------------------------|------------------------------|
|                | Marine sediment            | 2,9 mg/kg dry weight (d.w.)  |
|                | Soil                       | 0,63 mg/kg dry weight (d.w.) |
|                | Oral (Secondary Poisoning) | 380 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.

Use explosion-proof electrical, ventilating and lighting equipment.

#### Personal protective equipment

|                          |                                                                                                                                                                                                                                                                                                                  |
|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Eye/face protection      | : Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>Use appropriate degowning techniques to remove potentially contaminated clothing.                    |
| Respiratory protection   | : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.<br>Filter should conform to NS EN 14387                                                                                                   |
| 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

|                                                  |                     |
|--------------------------------------------------|---------------------|
| Physical state                                   | : liquid            |
| Colour                                           | : pink              |
| Odour                                            | : No data available |
| Odour Threshold                                  | : No data available |
| Melting point/freezing point                     | : No data available |
| Initial boiling point and boiling range          | : 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 |
| Flash point                                      | : 44 - 60 °C        |
| Auto-ignition temperature                        | : No data available |
| Decomposition temperature                        | : No data available |
| pH                                               | : No data available |
| Viscosity                                        |                     |
| Viscosity, kinematic                             | : No data available |
| Solubility(ies)                                  |                     |
| Water solubility                                 | : No data available |
| Partition coefficient: n-octanol/water           | : No data available |
| Vapour pressure                                  | : No data available |
| Relative density                                 | : No data available |
| Density                                          | : No data available |

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Relative vapour density : No data available

Particle characteristics  
Particle size : No data available

### 9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : 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 hazard classes as defined in Regulation (EC) No 1272/2008

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

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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

#### **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

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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.

#### 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.

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### 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                                                                               |
|                       |   | Test Type: Chromosome aberration test in vitro<br>Result: negative<br>Remarks: Based on data from similar materials                                                                                   |
|                       |   | Test Type: In vitro sister chromatid exchange assay in mammalian cells<br>Result: positive<br>Remarks: Based on data from similar materials                                                           |
| Genotoxicity in vivo  | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo 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 cytogenetic assay)<br>Species: Mouse<br>Application Route: Intraperitoneal injection<br>Result: negative |

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

##### Benzyl alcohol:

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

### Reproductive toxicity

Suspected of damaging fertility or the unborn child.

#### Components:

##### Pentobarbital sodium:

|                                    |                                                                                 |
|------------------------------------|---------------------------------------------------------------------------------|
| Reproductive toxicity - Assessment | : Some evidence of adverse effects on development, based on animal experiments. |
|------------------------------------|---------------------------------------------------------------------------------|

##### 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 |
|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------|

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Remarks: Based on data from similar materials

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.

### **Benzyl alcohol:**

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

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

### **STOT - single exposure**

Causes damage to organs.

#### **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:**

Species : Rat  
NOAEL : 1.730 mg/kg  
LOAEL : 3.200 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

#### **Phenytoin sodium:**



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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.

## **11.2 Information on other hazards**

### **Endocrine disrupting properties**

Not classified based on available information.

### **Product:**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### **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

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### SECTION 12: Ecological information

#### 12.1 Toxicity

##### 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 : EC50 (Ceriodaphnia dubia (water flea)): 5.012 mg/l  
aquatic invertebrates Exposure time: 48 h

Toxicity to algae/aquatic : ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l  
plants 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 tox- : NOEC: >= 79 mg/l  
icity) Exposure time: 100 d  
Species: Oryzias latipes (Japanese medaka)

Toxicity to daphnia and other : NOEC: 9,6 mg/l  
aquatic invertebrates (Chron- Exposure time: 9 d  
ic toxicity) 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  
aquatic invertebrates

##### **Benzyl alcohol:**

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

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

Toxicity to algae/aquatic : EC50 (Pseudokirchneriella subcapitata (green algae)): 770

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|                                                                        |                                                                                                                                                                                                |
|------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| plants                                                                 | 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                                                                               |

### 12.2 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 |
|------------------|--------------------------------------------------------------------------------------|

### 12.3 Bioaccumulative potential

#### Components:

##### **Ethanol:**

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

##### **Phenytoin sodium:**

|                                        |                                         |
|----------------------------------------|-----------------------------------------|
| Partition coefficient: n-octanol/water | : log Pow: 2,84<br>Remarks: Calculation |
|----------------------------------------|-----------------------------------------|

##### **Benzyl alcohol:**

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

### 12.4 Mobility in soil

No data available

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### 12.5 Results of PBT and vPvB assessment

#### **Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

#### **Product:**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

---

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                      |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product                | : Dispose of in accordance with local regulations.<br>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer.                                                                                                 |
| 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. |

---

## SECTION 14: Transport information

### 14.1 UN number or ID 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.<br>(Ethanol, Pentobarbital sodium) |
|-----|---------------------------------------------------------------|

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

### 14.3 Transport hazard class(es)

|             | Class | Subsidiary risks |
|-------------|-------|------------------|
| <b>ADN</b>  | : 3   |                  |
| <b>ADR</b>  | : 3   |                  |
| <b>RID</b>  | : 3   |                  |
| <b>IMDG</b> | : 3   |                  |
| <b>IATA</b> | : 3   |                  |

### 14.4 Packing group

|                                      |                     |
|--------------------------------------|---------------------|
| <b>ADN</b>                           |                     |
| Packing group                        | : III               |
| Classification Code                  | : F1                |
| Hazard Identification Number         | : 30                |
| Labels                               | : 3                 |
| <b>ADR</b>                           |                     |
| Packing group                        | : III               |
| Classification Code                  | : F1                |
| Hazard Identification Number         | : 30                |
| Labels                               | : 3                 |
| Tunnel restriction code              | : (D/E)             |
| <b>RID</b>                           |                     |
| Packing group                        | : III               |
| Classification Code                  | : F1                |
| Hazard Identification Number         | : 30                |
| Labels                               | : 3                 |
| <b>IMDG</b>                          |                     |
| Packing group                        | : III               |
| Labels                               | : 3                 |
| EmS Code                             | : F-E, <u>S-E</u>   |
| <b>IATA (Cargo)</b>                  |                     |
| Packing instruction (cargo aircraft) | : 366               |
| Packing instruction (LQ)             | : Y344              |
| Packing group                        | : III               |
| Labels                               | : Flammable Liquids |
| <b>IATA (Passenger)</b>              |                     |

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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 Maritime 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

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

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation : Not applicable

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(Annex XIV)

Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

|     |                   |                    |                     |
|-----|-------------------|--------------------|---------------------|
| H2  | ACUTE TOXIC       | Quantity 1<br>50 t | Quantity 2<br>200 t |
| P5c | FLAMMABLE LIQUIDS | 5.000 t            | 50.000 t            |

### Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

AICS : not determined

DSL : not determined

IECSC : not determined

## 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## 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.                                           |
| H317  | : May cause an allergic skin reaction.                            |
| H319  | : Causes serious eye irritation.                                  |
| H351  | : Suspected of causing cancer if swallowed.                       |
| 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. |

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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                              |
| Skin Sens.                | : Skin sensitisation                                 |
| STOT RE                   | : Specific target organ toxicity - repeated exposure |
| STOT SE                   | : Specific target organ toxicity - single exposure   |
| FOR-2011-12-06-1358       | : Norway. Occupational Exposure limits               |
| FOR-2011-12-06-1358 / TWA | : Long term exposure limit                           |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; 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; 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; 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

### 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/>



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### Classification of the mixture:

|                   |      |
|-------------------|------|
| Flam. Liq. 3      | H226 |
| Acute Tox. 3      | H301 |
| Skin Sens. 1      | H317 |
| 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                  |
| Calculation method                  |
| Calculation method                  |
| Calculation method                  |
| Calculation method                  |
| Calculation method                  |
| Calculation method                  |

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NO / EN