

## SECTION 1: Identification of the hazardous chemical and of the supplier

### 1.1 Product identifiers

Product name : Phenytoin (200 mg)

Product Number : 1535008

Brand : US Pharmacopeia

CAS-No. : 57-41-0

### 1.2 Other means of identification

No data available

### 1.3 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : For R&D use only. Not for pharmaceutical, household or other uses.

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

Company : SIGMA-ALDRICH (M) SDN BHD  
199701040579 (456079-T)  
No.4, Jalan U1/26, Section U1,  
HICOM GLENMARIE INDUSTRIAL PARK,  
40150 SHAH ALAM,  
MALAYSIA

Telephone : +60 (0)3-749-43688

Fax : +60 (0)3-749-10850

### 1.5 Emergency telephone number

Emergency Phone # : 1-800-815-308 (CHEMTREC) \* +60 3-9212 5794 (CHEMTREC Intl.)

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## SECTION 2: Hazards identification

### Classification of the hazardous chemical

Acute toxicity (Oral) : Category 4

Carcinogenicity : Category 2

Reproductive toxicity : Category 1B



**Label elements**

Hazard pictograms

:



Signal word

: Danger

Hazard statements

: H302 Harmful if swallowed.  
H351 Suspected of causing cancer.  
H360FD May damage fertility. May damage the unborn child.

Precautionary statements

: **Prevention:**P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P281 Use personal protective equipment as required.**Response:**

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth.

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards which do not result in classification**

May form explosible dust-air mixture if dispersed.

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**SECTION 3: Composition and information of the ingredients of the hazardous chemical**

Substance / Mixture

: Substance

CAS-No.

: 57-41-0

**Components**

| Chemical name | CAS-No. | Concentration (% w/w) |
|---------------|---------|-----------------------|
| phenytoin     | 57-41-0 | >= 60 -<= 100         |



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## SECTION 4: First aid measures

|                                                             |                                                                                                                                |
|-------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| General advice                                              | : Show this safety data sheet to the doctor in attendance.                                                                     |
| If inhaled                                                  | : After inhalation: fresh air. Call in physician.                                                                              |
| In case of skin contact                                     | : In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower. Consult a physician. |
| In case of eye contact                                      | : After eye contact: rinse out with plenty of water. Call in ophthalmologist. Remove contact lenses.                           |
| If swallowed                                                | : After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.                            |
| Most important symptoms and effects, both acute and delayed | : The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11          |
| Protection of first-aiders                                  | : For personal protection see section 8.                                                                                       |
| Notes to physician                                          | : No data available                                                                                                            |

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## SECTION 5: Firefighting measures

### Extinguishing media

|                                       |                                                                                |
|---------------------------------------|--------------------------------------------------------------------------------|
| Suitable extinguishing media          | : Water<br>Foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry powder             |
| Unsuitable extinguishing media        | : For this substance/mixture no limitations of extinguishing agents are given. |
| Specific hazards during fire fighting | : Combustible.                                                                 |

Risk of dust explosion.

Development of hazardous combustion gases or vapours possible in the event of fire.



Hazardous combustion products : Carbon oxides

Nitrogen oxides (NO<sub>x</sub>)

### **Special protective equipment and precautions for fire-fighters**

Special protective equipment for fire-fighters : Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

Specific extinguishing methods : Suppress (knock down) gases/vapours/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.

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## **SECTION 6: Accidental release measures**

Personal precautions, protective equipment and emergency procedures : Advice for non-emergency personnel:  
Avoid inhalation of dusts.  
Avoid substance contact.  
Ensure adequate ventilation.  
Evacuate the danger area, observe emergency procedures, consult an expert.  
Advice for emergency responders:  
For personal protection see section 8.

Environmental precautions : Do not let product enter drains.

Methods and materials for containment and cleaning up : Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10).  
Take up carefully. Dispose of properly. Clean up affected area.  
Avoid generation of dusts.

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## **SECTION 7: Handling and storage**

### **Handling**

For precautions see section 2.2.

### **Precautions for safe handling**

Advice on protection : Keep away from open flames, hot surfaces and



against fire and explosion : sources of ignition.  
Take precautionary measures against static discharge.

Advice on safe handling : Work under hood. Do not inhale substance/mixture.

## Storage

### Conditions for safe storage, including any incompatibilities

Further information on storage conditions : Tightly closed.  
Dry.  
Keep in a well-ventilated place.  
Keep locked up or in an area accessible only to qualified or authorised persons.

Storage class : 6.1C, Combustible, acute toxic Cat.3 / toxic compounds or compounds which causing chronic effects

Recommended storage temperature : Recommended storage temperature see product label.

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## SECTION 8: Exposure controls and personal protection

### Control parameters

Contains no substances with occupational exposure limit values.

**Appropriate engineering controls** : No data available

### Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection : Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).  
Safety glasses

Skin protection : protective clothing

#### Hand protection

Material : Nitrile rubber  
Break through time : 480 min  
Glove thickness : 0.11 mm  
Protective index : Full contact  
Manufacturer : KCL 741 Dermatril® L

Material : Nitrile rubber  
Break through time : 480 min  
Glove thickness : 0.11 mm  
Protective index : Splash contact  
Manufacturer : KCL 741 Dermatril® L



Remarks : This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN 16523-1 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: [www.kcl.de](http://www.kcl.de)).

Respiratory protection : required when dusts are generated.

Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system.

Recommended Filter type: : Filter type P3

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

Hygiene measures : Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance.

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## SECTION 9: Physical and chemical properties

Appearance : crystalline

Color : white

Odor : odourless

Odor Threshold : Not applicable

pH : No data available

Melting point/ range : 292 °C  
(ECHA)

Boiling point/boiling range : No data available

Flash point : Not applicable



|                                                     |                                                                                      |
|-----------------------------------------------------|--------------------------------------------------------------------------------------|
| Evaporation rate                                    | : No data available                                                                  |
| Flammability (solid, gas)                           | : May form combustible dust concentrations in air.                                   |
| Flammability (liquids)                              | : No data available                                                                  |
| Burning rate                                        | : No data available                                                                  |
| Upper explosion limit /<br>Upper flammability limit | : No data available                                                                  |
| Lower explosion limit /<br>Lower flammability limit | : No data available                                                                  |
| Vapor pressure                                      | : No data available                                                                  |
| Relative vapour density                             | : No data available                                                                  |
| Relative density                                    | : No data available                                                                  |
| Density                                             | : 1.26 g/cm <sup>3</sup>                                                             |
| Solubility(ies)<br>Water solubility                 | : slightly soluble (20 °C)                                                           |
| Partition coefficient: n-<br>octanol/water          | : log Pow: 2.47<br>Method: (experimental)<br>Bioaccumulation is not expected. (Lit.) |
| Autoignition temperature                            | : 550 °C                                                                             |
| Decomposition tempera-<br>ture                      | : No data available                                                                  |
| Viscosity, dynamic                                  | : No data available                                                                  |
| Viscosity, kinematic                                | : No data available                                                                  |
| Flow time                                           | : No data available                                                                  |
| Explosive properties                                | : Not classified as explosive.                                                       |
| Oxidizing properties                                | : none                                                                               |
| Molecular weight                                    | : 252.27 g/mol                                                                       |
| Minimum ignition energy                             | : < 10 mJ                                                                            |
| Particle characteristics<br>Particle size           | : No data available                                                                  |



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## SECTION 10: Stability and reactivity

|                                    |                                                                                                                                                                                             |
|------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reactivity                         | : The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed. |
| Chemical stability                 | : The product is chemically stable under standard ambient conditions (room temperature) .                                                                                                   |
| Possibility of hazardous reactions | : Violent reactions possible with:<br>Strong oxidizing agents<br>Water                                                                                                                      |
| Conditions to avoid                | : no information available                                                                                                                                                                  |
| Incompatible materials             | : No data available                                                                                                                                                                         |
| Hazardous decomposition products   | : In the event of fire: see section 5                                                                                                                                                       |

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Acute toxicity

LD50 Oral - Rat - 1,635 mg/kg

Remarks: Behavioral:Altered sleep time (including change in righting reflex).

Behavioral:Muscle weakness.

(RTECS)

Inhalation: No data available

Dermal: No data available

#### Skin corrosion/irritation

No data available

#### Serious eye damage/eye irritation

No data available

#### Respiratory or skin sensitization

No data available

#### Germ cell mutagenicity

Test Type: Ames test

Test system: Salmonella typhimurium

Metabolic activation: with and without metabolic activation

Result: negative

Remarks: (Lit.)

#### Carcinogenicity

Suspected of causing cancer.

#### Reproductive toxicity

May damage the unborn child.



May damage fertility.

**Specific target organ toxicity - single exposure**

No data available

**Specific target organ toxicity - repeated exposure**

No data available

**Aspiration hazard**

No data available

**11.2 Additional Information**

Gastrointestinal disturbance, Nausea, Dizziness, Headache, Ataxia., slurred speech, Blurred vision, nystagmus, Confusion., Hallucinations., insomnia  
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Systemic effects:

If swallowed

ataxia (impaired locomotor coordination)

somnolence

muscular weakness

After long-term exposure to the chemical:

Toxic effect on:

Liver

Kidney

Other dangerous properties can not be excluded.

Handle in accordance with good industrial hygiene and safety practice.

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**SECTION 12: Ecological information**

**Ecotoxicity**

**Components:**

**phenytoin:**

**Ecotoxicology Assessment**

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.



### **Persistence and degradability**

No data available

### **Bioaccumulative potential**

#### **Components:**

##### **phenytoin:**

Partition coefficient: n-octanol/water : log Pow: 2.47  
Method: (experimental)  
Remarks: Bioaccumulation is not expected.  
(Lit.)

### **Mobility in soil**

No data available

### **Other adverse effects**

#### **Components:**

##### **phenytoin:**

Additional ecological information : Discharge into the environment must be avoided.

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## **SECTION 13: Disposal information**

### **Disposal methods**

Waste from residues : Waste material must be disposed of in accordance with the national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

According to Quality Environment Regulation (Scheduled Waste) 2005, waste need to be sent to designated premise for recycle, treatment or disposal. Please contact Kualiti Alam for waste classification and correct disposal method.

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## **SECTION 14: Transport information**

### **International Regulations**

#### **IATA-DGR**

Not regulated as a dangerous good

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable



Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

**IMDG-Code**

Not regulated as a dangerous good  
UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : Not applicable

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**Special precautions for user**

Remarks : Not classified as dangerous in the meaning of transport regulations.

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**SECTION 15: Regulatory information**

**Safety, health, and environmental regulations specific for the hazardous chemical**

Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013.

Occupational Safety and Health (Use and Standards of Exposure of Chemicals Hazardous to Health) Regulations 2000.

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**SECTION 16: Other information**

Revision Date : 05.03.2026

**Further information**

Other information : The information is believed to be correct but is not exhaustive and will be used solely as a guideline, which is based on current knowledge of the chemical substance or mixture and is applicable to appropriate safety precautions for the product. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See [www.sigma-aldrich.com](http://www.sigma-aldrich.com) and/or the reverse side of invoice or packing slip for additional terms and condi-



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Date format : dd.mm.yyyy

### **Full text of other abbreviations**

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); EC<sub>x</sub> - Concentration associated with x% response; EL<sub>x</sub> - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErC<sub>x</sub> - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonised 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; IC<sub>50</sub> - 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 Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; KECI - Korea Existing Chemicals Inventory; LC<sub>50</sub> - Lethal Concentration to 50 % of a test population; LD<sub>50</sub> - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; 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 - Organisation 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

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MY / EN

US Pharmacopeia- 1535008

The life science business of Merck operates as MilliporeSigma in the US and Canada

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