

## Phenytoin

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

### SECTION 1. IDENTIFICATION

Product name : Phenytoin  
Mat.-No./ Genisys-No. : 20737879322

#### Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics  
-  
Address : 9115 Hague Road  
46250 Indianapolis IN  
Telephone : 1-800-428-5074  
Emergency telephone number:  
In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or  
Canada)  
1-703-527-3887 (International)

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

Restrictions on use : For professional users only.

---

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contains the resulting labelling for the kit.

#### GHS Label element

Not a hazardous substance or mixture.

#### Other hazards

None known.

---

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### R1 (A / B)

#### GHS Classification

Not a hazardous substance or mixture.

#### Hazardous components

No hazardous ingredients

#### R2 (C)

#### GHS Classification

Not a hazardous substance or mixture.

#### Hazardous components

No hazardous ingredients

## Phenytoin

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

### SECTION 4. FIRST AID MEASURES

General advice : Do not leave the victim unattended.

If inhaled : Move to fresh air.  
If unconscious place in recovery position and seek medical advice.  
If symptoms persist, call a physician.

In case of skin contact : If on skin, rinse well with water.

In case of eye contact : Immediately flush eye(s) with plenty of water.  
Remove contact lenses.  
Protect unharmed eye.  
If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Rinse mouth with water.

Most important symptoms and effects, both acute and delayed : No information available.

Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

### SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards during firefighting : No information available.

Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Refer to protective measures listed in sections 7 and 8.

Environmental precautions : Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).  
Keep in suitable, closed containers for disposal.

## Phenytoin

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

### SECTION 7. HANDLING AND STORAGE

Advice on safe handling : For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.

Conditions for safe storage : Electrical installations / working materials must comply with the technological safety standards.

Materials to avoid : No materials to be especially mentioned.

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### **R1 (A / B)**

##### **Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

#### **R2 (C)**

##### **Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

##### **Personal protective equipment**

Respiratory protection : No personal respiratory protective equipment normally required.

##### Hand protection

Material : Protective gloves  
Remarks : The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

##### Eye protection

: Safety glasses

##### Skin and body protection

: Protective suit

##### Hygiene measures

: Handle in accordance with good industrial hygiene and safety practice.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

#### **R1 (A / B)**

Appearance : liquid

## Phenytoin

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

pH	: 6.5
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Density	: 1.05 g/cm3
Solubility(ies)	
Water solubility	: completely miscible
Auto-ignition temperature	: No data available
Thermal decomposition	: No data available

### R2 (C)

Appearance	: liquid
pH	: 7.5
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Density	: 1.01 g/cm3
Solubility(ies)	
Water solubility	: completely miscible
Auto-ignition temperature	: No data available
Thermal decomposition	: No data available

## SECTION 10. STABILITY AND REACTIVITY

Reactivity	: No dangerous reaction known under conditions of normal use.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: Stable under recommended storage conditions. No hazards to be specially mentioned.
Conditions to avoid	: No data available

## Phenytoin

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

Incompatible materials : No data available

Hazardous decomposition products : No data available

## SECTION 11. TOXICOLOGICAL INFORMATION

### **R1 (A / B)**

#### **Information on likely routes of exposure**

#### **Acute toxicity**

Not classified based on available information.

#### **Product:**

Acute oral toxicity : Acute toxicity estimate : > 5,000 mg/kg  
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate : > 5,000 mg/kg  
Method: Calculation method

#### **Skin corrosion/irritation**

Not classified based on available information.

#### **Serious eye damage/eye irritation**

Not classified based on available information.

#### **Respiratory or skin sensitisation**

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

#### **Germ cell mutagenicity**

Not classified based on available information.

#### **Carcinogenicity**

Not classified based on available information.

#### **IARC**

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

#### **ACGIH**

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

#### **OSHA**

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

#### **NTP**

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

#### **Reproductive toxicity**

Not classified based on available information.

## Phenytoin

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Aspiration toxicity

Not classified based on available information.

### R2 (C)

### Information on likely routes of exposure

#### Acute toxicity

Not classified based on available information.

#### Skin corrosion/irritation

Not classified based on available information.

#### Serious eye damage/eye irritation

Not classified based on available information.

#### Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

#### Germ cell mutagenicity

Not classified based on available information.

#### Carcinogenicity

Not classified based on available information.

**IARC** No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**ACGIH** No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

**NTP** No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

Not classified based on available information.

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Aspiration toxicity

Not classified based on available information.

**Phenytoin**

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

**SECTION 12. ECOLOGICAL INFORMATION****R1 (A / B)****Ecotoxicity****Product:**

Ecotoxicology Assessment

Toxicity Data on Soil

: Not expected to adsorb on soil.

Other organisms relevant to  
the environment

: No data available

**Persistence and degradability**

No data available

**Bioaccumulative potential**

No data available

**Mobility in soil**

No data available

**Other adverse effects**

No data available

**Product:**

Regulation

40 CFR Protection of Environment; Part 82 Protection of  
Stratospheric Ozone - CAA Section 602 Class I Substances

Remarks

This product neither contains, nor was manufactured with a  
Class I or Class II ODS as defined by the U.S. Clean Air Act  
Section 602 (40 CFR 82, Subpt. A, App.A + B).**R2 (C)****Ecotoxicity****Product:**

Ecotoxicology Assessment

Toxicity Data on Soil

: Not expected to adsorb on soil.

Other organisms relevant to  
the environment

: No data available

**Persistence and degradability**

No data available

**Bioaccumulative potential**

No data available

**Mobility in soil**

No data available

**Other adverse effects**

No data available

**Product:**

## Phenytoin

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

Regulation	40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks	This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues	: Can be disposed as waste water, when in compliance with local regulations.
Contaminated packaging	: Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers.

## SECTION 14. TRANSPORT INFORMATION

### International Regulation

#### IATA-DGR

Not regulated as a dangerous good

#### IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

### National Regulations

#### 49 CFR

Not regulated as a dangerous good

## SECTION 15. REGULATORY INFORMATION

### R1 (A / B)

#### EPCRA - Emergency Planning and Community Right-to-Know Act

##### CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

\*: Calculated RQ exceeds reasonably attainable upper limit.

##### SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

\*: Calculated RQ exceeds reasonably attainable upper limit.

## Phenytoin

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

### SARA 302

: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

### SARA 313

: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### Clean Air Act

The following chemical(s) are listed as HAP under the U.S. Clean Air Act, Section 12 (40 CFR 61):

hydrogen chloride	7647-01-0	0.032 %
-------------------	-----------	---------

The following chemical(s) are listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F):

hydrogen chloride	7647-01-0	0.032 %
-------------------	-----------	---------

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMi Intermediate or Final VOC's (40 CFR 60.489).

### Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

hydrogen chloride	7647-01-0	0.032 %
sodium hydroxide	1310-73-2	0.009 %
disodium	7558-79-4	0.0035 PPM
hydrogenorthophosphat		
e		

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

hydrogen chloride	7647-01-0	0.032 %
sodium hydroxide	1310-73-2	0.009 %
disodium	7558-79-4	0.0035 PPM
hydrogenorthophosphat		
e		

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

### Massachusetts Right To Know

sodium azide	26628-22-8	0 - 0.1 %
hydrogen chloride	7647-01-0	0 - 0.1 %

### Pennsylvania Right To Know

water	7732-18-5	70 - 90 %
(carboxymethyl)trimethylammonium	590-47-6	20 - 30 %
hydroxide		
sodium azide	26628-22-8	0 - 0.1 %
hydrogen chloride	7647-01-0	0 - 0.1 %

### New Jersey Right To Know

water	7732-18-5	70 - 90 %
(carboxymethyl)trimethylammonium	590-47-6	20 - 30 %
hydroxide		
Sodium phosphate, monobasic, monohydrate	10049-21-5	1 - 5 %

### California Prop 65

: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

**R2 (C)**

## Phenytoin

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

### EPCRA - Emergency Planning and Community Right-to-Know Act

#### CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

\*: Calculated RQ exceeds reasonably attainable upper limit.

#### SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

\*: Calculated RQ exceeds reasonably attainable upper limit.

**SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

#### Clean Air Act

The following chemical(s) are listed as HAP under the U.S. Clean Air Act, Section 12 (40 CFR 61):

methanol	67-56-1	0.07 %
hydrogen chloride	7647-01-0	0.032 %

The following chemical(s) are listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F):

hydrogen chloride	7647-01-0	0.032 %
-------------------	-----------	---------

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMi Intermediate or Final VOC's (40 CFR 60.489):

methanol	67-56-1	0.07 %
----------	---------	--------

#### Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

hydrogen chloride	7647-01-0	0.032 %
sodium hydroxide	1310-73-2	0.009 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

hydrogen chloride	7647-01-0	0.032 %
sodium hydroxide	1310-73-2	0.009 %

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

#### Massachusetts Right To Know

sodium azide	26628-22-8	0 - 0.1 %
hydrogen chloride	7647-01-0	0 - 0.1 %

#### Pennsylvania Right To Know

water	7732-18-5	90 - 100 %
sodium azide	26628-22-8	0 - 0.1 %
methanol	67-56-1	0 - 0.1 %
hydrogen chloride	7647-01-0	0 - 0.1 %

#### New Jersey Right To Know

# SAFETY DATA SHEET



## Phenytoin

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

water

7732-18-5

90 - 100 %

### California Prop 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

methanol

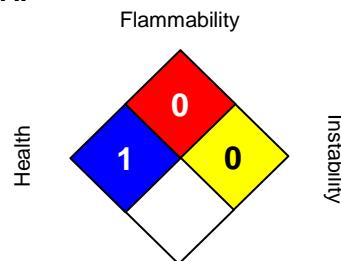
67-56-1

## SECTION 16. OTHER INFORMATION

### Further information

#### R1 (A / B)

NFPA:



Special hazard.

Health  
Instability

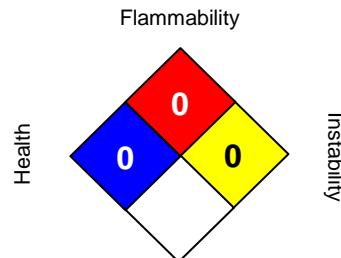
#### HMIS III:

HEALTH	2
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,  
2 = Moderate, 3 = High  
4 = Extreme, \* = Chronic

#### R2 (C)

NFPA:



Special hazard.

Health  
Instability

#### HMIS III:

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,  
2 = Moderate, 3 = High  
4 = Extreme, \* = Chronic

Revision Date

: 09-18-2014

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.