

Phenytoin

Safety Data Sheet

258431

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Version: 3.0

Date of issue: 04/09/2012 Revision date 08/01/2019

Supersedes 13/03/2017

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

1.1. Product identifier

Product form : Substance
Substance name : Phenytoin
IUPAC name : 5,5-Diphenylimidazolidine-2,4-dione
EC-No. : 200-328-6
CAS-No. : 57-41-0
Product code : 258431
Formula : C₁₅H₁₂N₂O₂
Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical, Pharmaceutical industry
Industrial/Professional use spec : For professional use only
Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals
Function or use category : Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - Nederland
T +31(0)23-5319093
farma@ducheffa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	+44 20 7188 7188	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral), Category 4 H302
Carcinogenicity, Category 2 H351
Reproductive toxicity, Category 1B H360

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS07

GHS08

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H302 - Harmful if swallowed.
H351 - Suspected of causing cancer.
H360 - May damage fertility or the unborn child.

Precautionary statements (CLP)

: P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312 - IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P330 - Rinse mouth.
P308+P313 - IF exposed or concerned: Get medical advice.

2.3. Other hazards

Other hazards not contributing to the classification : No additional information available.

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Phenytoin	(CAS-No.) 57-41-0 (EC-No.) 200-328-6	99 - 101	Acute Tox. 4 (Oral), H302 Carc. 2, H351 Repr. 1B, H360

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Assure fresh air breathing. Get medical advice and attention if you feel unwell.

First-aid measures after skin contact : Wash skin with mild soap and water.

First-aid measures after eye contact : Rinse with water. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Seek medical advice.

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

Symptoms/effects : Breathing difficulties. May cause an allergic skin reaction. Nervous system disorder.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : All extinguishing agents can be used.

5.2. Special hazards arising from the substance or mixture

Fire hazard : No fire hazard.

Explosion hazard : Product is not explosive.

Hazardous decomposition products in case of fire : Nitrogen oxides. Carbon monoxide. Carbon dioxide.

5.3. Advice for firefighters

Precautionary measures fire : Exercise caution when fighting any chemical fire.

Firefighting instructions : Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid raising dust. Ensure adequate ventilation.

6.1.1. For non-emergency personnel

Protective equipment : Use the personal protective equipment as indicated in chapter 8.

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up, shovel or vacuum. Hose down area with water.

6.4. Reference to other sections

See Heading 8. See Heading 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures. Ensure good ventilation of the work station.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area. Keep container tightly closed.
Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

No additional information available

8.2. Exposure controls**Appropriate engineering controls:**

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Hand protection:

Chemical resistant PVC gloves (to European standard EN 374 or equivalent)

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Dustmask with filtertype P3

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state : Solid
Appearance : Crystalline powder.
Molecular mass : 252.3 g/mol
Colour : White.
Odour : odourless.
Odour threshold : No data available
pH : No data available
Relative evaporation rate (butylacetate=1) : No data available
Melting point : 292 - 296 °C
Freezing point : No data available
Boiling point : No data available
Flash point : 585 °C
Auto-ignition temperature : > 300 °C
Decomposition temperature : No data available
Flammability (solid, gas) : No data available

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Vapour pressure : No data available
Relative vapour density at 20 °C : No data available
Relative density : No data available
Density : 0.2 - 0.3 g/ml
Solubility : Practically insoluble in alcohol. Insoluble in water.

Log Pow : No data available
Viscosity, kinematic : No data available
Viscosity, dynamic : No data available
Explosive properties : No data available

Oxidising properties : No data available
Explosive limits : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity**10.1. Reactivity**

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal conditions.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Strong bases.

10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide. Nitrogen oxides.

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

Acute toxicity : Oral: Harmful if swallowed.

Phenytoin (57-41-0)	
LD50 oral rat	1635 mg/kg
Additional information	TDLo/oral/woman 3203 mg/kg (1-39W pregnancy)

Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Not classified
Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Suspected of causing cancer.

Reproductive toxicity : May damage fertility or the unborn child.

STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information**12.1. Toxicity**

Ecology - general : There are no available data for a classification.

12.2. Persistence and degradability

Phenytoin (57-41-0)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Phenytoin (57-41-0)	
Bioaccumulative potential	No bioaccumulation data available.

12.4. Mobility in soil

Phenytoin (57-41-0)	
Ecology - soil	There are no available data for a classification.

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other adverse effects : None known.

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Regional legislation (waste) : Disposal must be done according to official regulations.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
Not applicable	Not applicable
14.2. UN proper shipping name	
Not applicable	Not applicable
14.3. Transport hazard class(es)	
Not applicable	Not applicable
Not applicable	Not applicable
14.4. Packing group	
Not applicable	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user**- Overland transport**

No data available

- Air transport

No data available

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Phenytoin is not on the REACH Candidate List

Phenytoin is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1.4	Emergency telephone	Modified	Added additional information
2	Classification (DSD/DPD)	Removed	Obsolete
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Removed	
2.3	Other hazards not contributing to the classification	Added	
4.2	Symptoms/effects	Modified	
7.2	Storage temperature	Added	
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves
8.2	Respiratory protection	Modified	
9.1	Auto-ignition temperature	Added	
11.1	Additional information	Added	

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
LC50	Median lethal concentration

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LD50	Median lethal dose
vPvB	Very Persistent and Very Bioaccumulative

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Carc. 2	Carcinogenicity, Category 2
Repr. 1B	Reproductive toxicity, Category 1B
H302	Harmful if swallowed.
H351	Suspected of causing cancer.
H360	May damage fertility or the unborn child.

SDS EU (REACH Annex II) Version 2018

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product