

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

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PHENYTOINUM NATRICUM

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name:	Phenytoin sodium Phenytoinum natricum Natriumfenytoïne Phénytoïne sodique Phenytoin-Natrium
N° CAS:	630-93-3
N° EC:	211-148-2

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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1.3 Details of the supplier of the safety data sheet

Company:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute Tox. 4	H302
Skin Sens. 1	H317
Carc. 2	H351
Repr. 2	H361d
STOT RE 2	H373
Eye Irrit .2	H319

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



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Signal word(s):	Attention
Hazard statements:	
H302	Harmful if swallowed.
H317	May cause allergic skin reaction.
H351	Suspected of causing cancer.
H361d	Suspected of damaging the unborn child.
H373	May cause damage to central nervous system through prolonged or repeated exposure.
H319	Causes serious eye irritation.
Precautionary statements:	
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P321	Specific treatment (see on this label).
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/inter-national regulations.
Additional applicable label elements:	

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Phenytoin sodium
IUPAC name:	Sodium 4-oxo-5,5-diphenyl-4,5-dihydro-1H-imidazol-2-olate
Synonyms:	5,5-Diphenylhydantoin, Sodium Salt Diphenylhydantoin sodium Antisacer
N° CAS:	630-93-3
N° EC:	211-148-2
Molecular Formula:	C ₁₅ H ₁₁ N ₂ NaO ₂
Content:	98.0 per cent to 102.0 per cent (anhydrous substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

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After inhalation:	Allow victim to rest in a well-ventilated area. Seek immediate medical attention. Serious inhalation: Evacuate the victim to a safe area as soon as possible. Loosen tight clothing such as a collar, tie, belt or waistband. If breathing is difficult, administer oxygen. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek medical attention.
After skin contact:	After contact with skin, wash immediately with plenty of water. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases and groin. Cover the irritated skin with an emollient. If irritation persists, seek medical attention. Wash contaminated clothing before reusing. Serious skin contact: Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek immediate medical attention.
After eye contact:	Check for and remove any contact lenses. Do not use an eye ointment. Seek medical attention.
After ingestion:	Do not induce vomiting. Examine the lips and mouth to ascertain whether the tissues are damaged, a possible indication that the toxic material was ingested; the absence of such signs, however, is not conclusive. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Gastrointestinal disturbance, nausea, dizziness, headache, ataxia. Blurred vision, confusion, hallucinations. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Small fire: Use DRY chemical powder. Large fire: Use water spray, fog or foam.
Unsuitable extinguishing media:	Do not use water jet.

5.2 Special hazards arising from the substance/mixture

Flammability of the product: may be combustible at high temperature.
Products of combustion: These products are carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂ ...). Some metallic oxides.

5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Splash goggles. Lab coat. Gloves. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate. Personal protection in case of a large spill: Large spill means large volume (more than five kg) packed drum breakage and powder spill on floor. Then use splash goggles. Full suit. Respiratory protection – the use of an approved air purifying respirator with a HEPA cartridge

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(P100 or equivalent) and an organic vapour cartridge may be needed if excess volatiles are generated. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist before handling this product.

Hazardous combustion products:

Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

For emergency responders

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. See section 5.3 (protection against fire).

6.2 Environmental precautions

Not available.

6.3 Methods and material for containment and cleaning up

Pick up and arrange disposal without creating dust.

Sweep up and shovel.

Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Keep locked up. Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes.

Personal protection:

Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment.

Technical protective measures:

Ground all equipment containing material.

Handling:

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

In an airtight container.

Conditions for safe storage, including any incompatibilities:

Keep container dry. Keep in a cool place. Ground all equipment containing material. Keep container tightly closed. Keep in a cool,

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Storage – away from:

well-ventilated place. Highly toxic or infectious materials should be stored in a separate locked safety storage cabinet or room.

Not available.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures

Eye/face protection: Splash goggles.

In case of a large spill: Splash goggles.

Skin protection: Lab coat.

In case of a large spill: Full suit. Boots.

Hand protection: Gloves.

In case of a large spill: Gloves.

Respiratory protection: Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate.

In case of a large spill: A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White or almost white, very hygroscopic, crystalline powder.

Odour: Not available.

Odour threshold: Not available.

pH: Not available.

Melting/freezing point: Decomposes.

Initial boiling point: Not available.

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Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	May be combustible at high temperature.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not applicable.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Soluble in ethanol (96 per cent), practically insoluble in methylene chloride.
Solubility in water:	Soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

The product is stable.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Exposure to light and freezing. Prevent vapour accumulation. Keep away from heat, sparks, flames and all other sources of ignition.

10.5 Incompatible materials

Strong oxidisers.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

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Acute toxicity:	Oral LD ₅₀ (mouse): 165 mg/kg
Skin corrosion/irritation:	Hazardous in case of skin contact (irritant).
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Routes of entry: Absorbed through skin, eye contact, inhalation, ingestion.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Hazardous in case of skin contact (irritant).
Inhalation:	Hazardous in case of inhalation.
Ingestion:	Hazardous in case of ingestion. Harmful if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Products of biodegradation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the products of biodegradation: The products of degradation are more toxic.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

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13.1 Waste treatment methods

Description of waste residues and information on their safe handling and methods of disposal, including any contaminated packing: Dispose of as unused product.

Waste disposal: Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), UN 2811
IATA/ICAO (Air) :

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), Toxic solids, organic, n.o.s. (Phenytoin sodium)
IATA/ICAO (Air) :

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), 6.1
IATA/ICAO (Air) :

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), III
IATA/ICAO (Air) :

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), Marine pollutant: No.
IATA/ICAO (Air) :

14.6 Special precautions for user

Not applicable.

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

Not applicable.

14.8 Additional transport information

DOT Classification: Not a DOT controlled material (United States).

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Irritant
Harmful

Risk phrases:

R22 Harmful if swallowed.
R36 Irritating to eyes.

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Safety phrases:

R43 May cause sensitization by skin contact.

R48 Danger of serious damage to health by prolonged exposure.

R63 Possible risk of harm to the unborn child.

S1 Keep locked up.

S23 Do not breathe dust/fume/gas/mist/vapours/spray.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals

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Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

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