


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	PHENYTOIN SODIUM, USP/EP
PRODUCT CODE	0216
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 4) Sensitization - Skin (Category 1) Toxic to Reproduction (Category 1B) Carcinogenicity (Category 2) Chronic Aquatic Toxicity (Category 2)
PICTOGRAM	
SIGNAL WORD	Danger
HAZARD STATEMENT(S)	Harmful if swallowed. May cause an allergic skin reaction. May damage fertility or the unborn child. Suspected of causing cancer. May cause allergic reaction. Toxic to aquatic life with long lasting effects.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Repeated exposure may cause skin dryness or cracking.

PRECAUTIONARY STATEMENT(S)	Prevention	Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid breathing dust, fume, gas, mist, vapors, and spray. Contaminated work clothing should not be allowed out of the workplace. Obtain, read and follow all special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye and face protection and hearing protection. Avoid release to the environment.	
	Response	IF SWALLOWED: Immediately call a poison center. Get medical help. Rinse mouth. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical help advice/attention. Take off contaminated clothing and wash it before reuse. IF EXPOSED OR CONCERNED: Get medical advice. COLLECT SPILLAGE.	
	Storage	Store locked up.	
	Disposal	Dispose of contents and/or container in accordance with local regulations.	
HMS CLASSIFICATION	Health Hazard	2	Flammability 1
	Reactivity	0	Personal Protection E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	2,4-Imidazolidinedione, 5,5-diphenyl-, monosodium salt
BOTANICAL NAME	Not applicable
SYNONYM	5,5-Diphenylhydantoin sodium salt; Diphenylhydantoin sodium
CHEMICAL FORMULA	C ₁₅ H ₁₁ N ₂ NaO ₂
CHEMICAL FAMILY	Hydantoin
CAS NUMBER	630-93-3
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	274.2539

COMPOSITION

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
PHENYTOIN SODIUM	630-93-3	211-148-2	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.
MEDICAL ATTENTION AND SPECIAL TREATMENT	Get emergency medical help.

SYMPTOMS CAUSED BY
EXPOSURE

Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING
FROM THE CHEMICAL

Not applicable

FLAMMABLE PROPERTIES

May be combustible at high temperature.

HAZARDOUS COMBUSTION
PRODUCTS

Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE
EXTINGUISHING MEDIA

Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND
PRECAUTIONS FOR
FIREFIGHTERS

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR
CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER
SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE
HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE
STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40°C are acceptable.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION
Chemical Name: PHENYTOIN SODIUM CAS #: 630-93-3

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

 Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³
PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

NOTES

 USP: Industrial: ELV: TWA 0.4 mg/m³
SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
PHYSICAL STATE

Solid

DESCRIPTION

White or almost white, very hygroscopic, crystalline powder. Is odorless.

SOLUBILITY

Freely soluble in water, the solution usually being somewhat turbid due to partial hydrolysis and absorption of carbon dioxide; soluble in alcohol; practically insoluble in ether and in chloroform.

ODOR

Odorless

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

Not available

BOILING POINT

Not available

DECOMPOSITION TEMPERATURE

Not available

EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available	FLASH POINT	Not available
log P (OCTANOL-WATER)	Not available	LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	>300 °C, >572 °F
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	11.7 (saturated solution)
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	Not available	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	< 0.000001 kPa (25°C)	VISCOSITY	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established.
CHEMICAL STABILITY	Stable under recommended storage conditions. Upon exposure to air gradually absorbs carbon dioxide.
INCOMPATIBLE MATERIALS	Strong oxidants. Water. Acids.
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur.
HAZARDOUS POLYMERIZATION	Will not occur.
POSSIBILITY OF HAZARDOUS REACTION	Not established.
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 1530 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Due to lack of data the classification is not possible.
SERIOUS EYE DAMAGE/EYE IRRITATION	Due to lack of data the classification is not possible.
RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible.
SKIN SENSITIZATION	May cause sensitization by skin contact.

GERM CELL MUTAGENICITY

Based on available data, the classification criteria are not met.
Mutagenicity
500 mg/kg Chromosomal aberration study in mouse bone marrow cells
Result: Negative.

Chromosomal aberration study in Chinese hamster ovary cells
Result: Negative.

In vivo assays in human lymphocytes
Result: Negative for micronucleus formation and sister chromatid exchange.

In vivo mouse micronucleus test
Result: Positive.

S. typhimurium Ames assay
Result: Positive.

CARCINOGENICITY

OSHA PHENYTOIN SODIUM is listed.

NTP PHENYTOIN SODIUM is listed.

IARC PHENYTOIN is listed in group 2b (possibly carcinogenic to humans).

California Proposition This product contains the following chemical known to the State of California to cause cancer: PHENYTOIN SODIUM.

ADDITIONAL CARCINOGENICITY INFORMATION

Suspected of causing cancer.
Animal studies have shown this material to be carcinogenic in rodents.

REPRODUCTIVE TOXICITY

Overexposure may cause reproductive disorder(s) based on tests with laboratory animals.
Possible risk of congenital malformation in the fetus.
Suspected human reproductive toxicant.

100 mg/kg Reproductivity and development study
Result: Performance and learning deficits in offspring.
Species: Rat

60 - 600 mg/kg Reproductivity and development study
Result: Maternal toxicity and embryotoxicity.
Species: Monkey

75 mg/kg Reproductivity and development study
Result: Teratogenicity.
Species: Mouse

75 mg/kg Reproductivity and development study, administered during gestation.
Result: Increased resorption and malformation rates.
Species: Rabbit

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Due to lack of data the classification is not possible.

ASPIRATION HAZARDS

Based on available data, the classification criteria are not met.

**SIGNS AND SYMPTOMS OF
EXPOSURE**

ROUTES OF EXPOSURE:

Oral, Dermal, Inhalation, Eye contact

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Not available

Symptoms related to the physical, chemical, and toxicological characteristics:

Hydantoin anticonvulsants: Central nervous system depression. Mental or mood changes. Nausea. Rash. Uncontrolled eye movements. Dizziness.

An antiepileptic hypersensitivity syndrome, comprising fever, rash, and lymphadenopathy and less commonly lymphocytosis, and liver and other organ involvement, has been associated with some antiepileptic drugs including phenytoin. Most cases resolve spontaneously on withdrawal of the drug and symptomatic management.

POTENTIAL HEALTH EFFECTS**Inhalation**

May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion

Harmful if swallowed. Based on information from therapeutic use, this material may cause: Cardiovascular effects.

Skin

May be harmful if absorbed through skin. May cause skin irritation. May cause an allergic skin reaction.

Eyes

May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION**ECOTOXICITY**

EC50: 48 Hr: Crustacea: Daphnia: (mg/L): 5.93*

LC50: 96 Hr: Fish: (mg/L): 25.12*

EC50: 96 Hr: Green Algae: (mg/L): <1*

**PERSISTENCE AND
DEGRADABILITY**

Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable.

BIOACCUMULATIVE POTENTIAL

Not available.

MOBILITY IN SOIL

Freely soluble in water.

OTHER ADVERSE EFFECTS

Not available.

NOTES

This product is not intended to be released into the environment.

*Danish QSAR database.

SECTION 13: DISPOSAL CONSIDERATIONS**DISPOSAL METHODS**

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION**UN PROPER SHIPPING NAME**

Not dangerous good

UN NUMBER

Not applicable

CLASS

Not applicable

PACKING GROUP

Not applicable

AUSTRALIA
HAZCHEM

Not applicable

EU
**TRANSPORT IN BULK ACCORDING
TO ANNEX II OF MARPOL 73/78
AND THE IBC CODE**

Not listed

ENVIRONMENTAL HAZARDS

Not available

**SPECIAL SHIPPING
INFORMATION**

Not applicable

SECTION 15: REGULATORY INFORMATION
UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
PHENYTOIN SODIUM 630-93-3	N/L	N/L	N/L	N/L	X	X*	N/L	X

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
PHENYTOIN SODIUM 630-93-3	N/L	Listed as Schedule 4*	N/L	Listed*	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
PHENYTOIN SODIUM 630-93-3	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

**SUBJECT TO INTERNATIONAL
AGREEMENT**

Not applicable

NOTES

*Listed as the base

SECTION 16: OTHER INFORMATION
REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

03/2023

SUPERSEDES

05/2021

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.