MATERIAL SAFETY DATA SHEET

SECTION 1 - CHEMICAL PRODUCT & COMPANY IDENTIFICATION

Pfizer Inc
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Hours of operation 24 hours

Trade names	**Dilantin®**
Product name	**Dilantin-125® (Phenytoin Oral Suspension)**
Therapeutic use	Treatment of seizures and epilepsy
Description	Orange suspension

SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS Number	Amount
Phenytoin*	57-41-0	7.4%
Ethyl alcohol (ethanol), USP*	64-17-5	<1.0%
Sucrose*	57-50-1	Trade secret
Glycerin*	56-81-5	Trade secret
Sodium carboxymethyl cellulose	9004-32-4	Trade secret
Magnesium aluminum silicate*	1327-43-1	Trade secret
Sodium benzoate	532-32-1	Trade secret
Polysorbate 40	9005-66-7	Trade secret
Vanillin*	121-33-5	Trade secret
Imitation banana oil	Not assigned	Trade secret
Concentrated orange oil	8008-57-9	Trade secret
Citric acid*	77-92-9	Trade secret
Purified water	7732-18-5	Trade secret
FD&C Yellow No. 6	2783-94-0	Trade secret

*Hazardous

Note: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

SECTION 3 - HAZARDS IDENTIFICATION

Signal word **CAUTION!**

SECTION 3 - HAZARDS IDENTIFICATION ... continued

Statements of hazard	**MAY BE HARMFUL IF SWALLOWED** **ANTIEPILEPTIC DRUG: MAY CAUSE NERVOUS SYSTEM EFFECTS** **MAY CAUSE ADVERSE EFFECTS ON FETAL DEVELOPMENT** **POSSIBLE CARCINOGEN**
Eye effects	May cause irritation based on components.
Skin effects	May cause irritation based on components.
Inhalation effects	An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).
Ingestion effects	May be harmful if swallowed. Accidental ingestion may cause effects similar to those seen in clinical use. See 'Statements of hazard', 'Known clinical effects', and/or 'Other potential health effects' in this section.
Known clinical effects	The most common adverse effects observed with clinical use of phenytoin are lack of appetite, headache, dizziness, transient nervousness, ataxia, slurred speech, decreased coordination, mental confusion, insomnia, and GI disturbances (nausea, vomiting, and constipation). IV administration has been associated with hypotension and CNS depression. Mild hypersensitivity reactions (skin rashes) are common. Effects on blood-forming organs and the liver have occurred rarely.
Other potential health effects	Occupational handling of phenytoin has resulted in a tasting of this material or a "tickling" sensation in the back of the phrarynx. Increased frequencies of major malformations, minor anomalies, growth abnormalities, mental deficiency, and malignancies have been reported among children born to women who took phenytoin during pregnancy. Clinical use of phenytoin has been associated with enlargement of certain tissues, such as lymphatic and gum tissues.

SECTION 4 - FIRST AID MEASURES

Eyes	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
Skin	Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

SECTION 4 - FIRST AID MEASURES ... continued

Ingestion	Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

SECTION 5 - FIRE FIGHTING MEASURES

Fire fighting instructions	Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.
Extinguishing media	Use carbon dioxide, dry chemical, or water spray.
Hazardous combustion products	Emits toxic fumes of carbon monoxide and oxides of nitrogen
Flash point	No data available

SECTION 6 - ACCIDENTAL RELEASE MEASURES

General	Review Sections 3, 8 and 12 before proceeding with clean up.
Small spill	Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal. Clean spill area thoroughly.
Large spill	Collect spill with a non-combustible absorbent material. Transfer all waste to a labeled container and move it to a secure holding area.

SECTION 7 - HANDLING AND STORAGE

General handling	Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist.
Storage conditions	Protect from freezing and light
Temperature range for storage	Store at controlled room temperature 20-25°C (68-77°F)

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits

Compound	Issuer	Type	OEL
Phenytoin	Pfizer	TWA-8 Hr	0.4 mg/m³
Sucrose	OSHA	TWA-8 Hr	15 mg/m³ (total dust)
	OSHA	TWA-8 Hr	5 mg/m³ (respirable fraction)
	ACGIH	TWA-8 Hr	10 mg/m³
Glycerin	ACGIH	TWA-8 Hr	10 mg/m³ (mist)
	OSHA	TWA-8 Hr	15 mg/m³ (mist)-total dust

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ... continued

Exposure limits ...
continued

Compound	Issuer	Type	OEL
	OSHA	TWA-8 Hr	5 mg/m³ (mist)- respirable fraction
Sodium carboxymethyl cellulose	ACGIH	TWA-8 Hr	10 mg/m³ (inhalable particulate)
	ACGIH	TWA-8 Hr	3 mg/m³ (respirable particulate)
	OSHA	TWA-8 Hr	15 mg/m³ (total dust)
Magnesium aluminum silicate	ACGIH	TWA-8 Hr	10 mg/m³ (inhalable particulate)
	ACGIH	TWA-8 Hr	3 mg/m³ (respirable particulate)
	OSHA	TWA-8 Hr	15 mg/m³ (total dust)
	OSHA	TWA-8 Hr	5 mg/m³ (respirable dust)

Exposure information See exposure limits for component (s) listed above.

Analytical method Phenytoin: SAM #048.2 (contact Pfizer for additional details).

Ventilation Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.

Eye protection Safety glasses or goggles.

Skin protection Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Hand protection Rubber gloves

Respiratory protection If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical form Suspension

Color Orange

Taste Orange-vanilla

Melting point Not applicable

Water solubility No data available

Solvent solubility No data available

SECTION 10 - STABILITY AND REACTIVITY

Reactivity Stable under normal conditions of use.

Conditions to avoid None known

SECTION 10 - STABILITY AND REACTIVITY ... continued

Incompatibilities None known

Hazardous polymerization Will not occur

SECTION 11 - TOXICOLOGY INFORMATION

Toxicology summary The information included in this section describes the potential hazards of the active ingredient.

Acute toxicity

Compound	Type	Route	Species	Result
Phenytoin	LD_{50}	Oral	Mouse	150 mg/kg
	LD_{50}	Oral	Rat	1635 mg/kg

Eye Phenytoin may be irritating to eyes based on local effects seen in injection studies.

Skin Phenytoin may be irritating to skin based on local effects seen in injection studies.

Inhalation No data available

Ingestion See Acute toxicity table.

Mutagenicity This material was not mutagenic in bacterial cells and not clastogenic in mammalian cells *in vitro*. Positive *in vivo* in the sister chromatid exchange assay with human lymphocytes.

Sensitization Hypersensitivity reactions to phenytoin and other hydantoins have been reported.

Subchronic effects Repeat-dose studies of phenytoin in mice and rats have produced death at high doses (1,200-30,000 ppm/day) along with depletion of bone marrow elements and reduced body weight gain. Effects seen in mice only included hyperplasia and/or hyperkeratosis of the stomach and megalocytosis of the liver as well as lymphoid depletion in the spleen.

Chronic effects/ carcinogenicity In a two-year dietary carcinogenicity study conducted with phenytoin, an increased incidence of liver tumors was seen in mice receiveing 45 mg/kg/day. In the IARC monograph for for phenytoin and phenytoin sodium it is also reported that oral administration of 60 mg/kg/day caused an increased incidence of thymic or generalized lyphomas in mice.

Carcinogen status See below

NTP carcinogen Group 2 (reasonably anticipated to be a human carcinogen)

IARC carcinogen 2B (possibly carcinogenic to humans)

SECTION 11 - TOXICOLOGY INFORMATION ... continued

Teratogenicity	Phenytoin has been shown to cause developmental toxicity in mice, rats, rabbits, and monkeys. Effects seen include cleft lip, with or without cleft palate, shortened long bones, hydronephrosis with renal hemorrhaging, delayed ossification of the axial skeleton, neural tube defects, and cardiac, digital and ocular abnormalities.
At increased risk from exposure	This material has been shown to be secreted in low concentrations in human breast milk. Women of childbearing age or nursing mothers should exercise caution regarding exposure.
Additional information	There is an unconfirmed association between the use of anticonvulsants during pregnancy and an increased risk of birth defects. However, due to confounding factors such as concomitant use of other drugs and the individual's disease state, a cause and effect relationship has not been conclusively established.

SECTION 12 - ECOLOGICAL INFORMATION

Environmental overview	The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

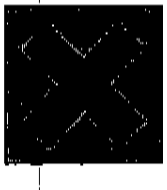
SECTION 13 - DISPOSAL INFORMATION

Disposal procedure	Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this mixture.

SECTION 14 - TRANSPORTATION INFORMATION

General shipping instructions	Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

SECTION 15 - REGULATORY INFORMATION

California Proposition 65	Phentyoin
EU Classification	Carcinogenic: Category 3; Toxic to Reproduction; Category 3
EU Labelling	**Xn**
EU Label Pictogram	

SECTION 15 - REGULATORY INFORMATION ... continued

Risk phrases	R40 - Limited evidence of a carcinogenic effect. R63 - Possible risk of harm to the unborn child.
Safety phrases	S22 - Do not breathe dust. S36/37 - Wear suitable protective clothing and gloves. S53 - Avoid exposure - obtain special instructions before use.
WHMIS Classification	Class D, Division 2, Subdivision A

SECTION 16 - OTHER

Disclaimer	**Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate. While Pfizer provides this information in good faith, it does not expressly or impliedly warrant its accuracy.**