



Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Dexamethasone USP Micronized

55-1081

Section 1: Identification

Product Name Dexamethasone USP Micronized

Commercial Name Not available.

Product Use Pharmaceutical active

Restrictions On Use Not available.

Product Code 55-1081

Company PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300

Section 2: Hazard(s) Identification

OSHA Haz Com: Reproductive Toxicity: Category 1B Combustible dust.
CFR 1910.1200

Signal Word DANGER

Hazard Statement(s) MAY DAMAGE THE UNBORN CHILD. MAY CAUSE DAMAGE TO ORGANS THROUGH PROLONGED OR REPEATED EXPOSURE. VERY TOXIC TO AQUATIC LIFE WITH LONG LASTING EFFECTS. MAY FORM COMBUSTIBLE DUST CONCENTRATIONS IN AIR.

Pictogram(s) or Symbol(s)



Precautionary Statement(s):

Prevention P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P281 Use personal protective equipment as required.
Response P308 + P313 IF exposed or concerned: Get medical advice/attention.
Storage P405 Store locked up.
Disposal P501 Dispose of contents/container in accordance with all local and national regulations.

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components Dexamethasone USP Micronized
% By Weight 100
CAS# 50-02-2
Molecular Weight 392.47 g/mole
Chemical Formula C₂₂H₂₉FO₅
Synonym(s) Fluoro-9-trihydroxy-11,17,21-methy -16-pregnadiene-1

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Dexamethasone USP Micronized	50-02-2	100	Not Available.	ORAL (LD50): Acute: 3000 mg/kg [Rat].

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Section 4: First-Aid Measures

Inhalation	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.
Skin Contact	Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.
Eye Contact	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
Ingestion	Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
Symptoms/Effects	
Acute	Not available.
Delayed	Not available.
Immediate Medical Attention	Not available.

Section 5: Fire-Fighting Measures**Suitable Extinguishing Media**

Extinguish fires with CO₂, extinguishing powder, foam, or water.

Unsuitable Extinguishing Media

Not available.

Products of Combustion

Formation of toxic gases is possible during heating or fire. May include oxides of carbon and products of fluorine.

Firefighters Special Equipment and Precautions

Fine particles (such as dust and mists) may fuel fires/explosions. During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Environmental Precautions: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. Methods and Material for Containment and Cleaning Up Measures for Cleaning /Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly. Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Section 7: Handling and Storage

Precautions for Safe Handling: Restrict access to work area. Avoid open handling. Ground and bond all bulk transfer equipment. Minimize dust generation. Use process containment, local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

Section 8: Exposure Controls/Personal Protection

Exposure Limits	Pfizer OEL TWA-8 Hr: 3µg/m ³
Engineering Controls	Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.



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Personal Protection

Hands: Wear impervious gloves as minimum protection. Eyes: Wear safety glasses as minimum protection. Skin: Wear impervious protective clothing when handling this compound. 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

Appearance	White solid. (Powdered solid.)				
Odor	Odorless.				
Odor Threshold	Not available.				
Melting Point	262-264		pH	Not available.	
Freezing Point	Not available.		Vapor Pressure	Not applicable.	
Boiling Point/Range	Not available.		Vapor Density	Not available.	
Decomposition temperature	Not available.		Viscosity	Not available.	
Partition Coefficient: n-octanol/water	Predicted	Log P	1.78	Evaporation Rate	Not available.
Flash Point	Not available.		Autoignition temperature	Not available.	
Flammability	Not available.		Flammability or Explosive Limits:		
			Lower	Not available.	
			Upper	Not available.	
Solubility(ies)	Soluble: Alcohol, Acetone, Dioxane, Chloroform, Ether; water: 10 mg/100 ml				
Other	Not available.				

Section 10: Stability and Reactivity

Reactivity	Not available.
Chemical Stability	Stable under normal conditions of use.
Hazardous Polymerization	Not available.
Conditions to Avoid	Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources.
Incompatible Materials	As a precautionary measure, keep away from strong oxidizers.
Hazardous Decomposition Products	Not available.

Section 11: Toxicological Information
RTECS TU3980000

Acute Toxicity

Dexamethasone Rat Oral LD 50 > 3000 mg/kg Rat Intraperitoneal LD 50 54 mg/kg Rat Subcutaneous LD 50 14 mg/kg Mouse Intraperitoneal LD 50 410 mg/kg Mouse Subcutaneous LD 50 4400 mg/kg Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test. Dexamethasone Eye Irritation Rabbit Mild Skin Irritation Rabbit Mild Dexamethasone 90 Day(s) Rat Oral 0.003 mg/kg/day LOAEL Adrenal gland 13 Week(s) Rat Subcutaneous 40 Ng/kg/day LOAEL Adrenal gland, Thymus 26 Week(s) Rat Oral 0.125 mg /kg/day LOAEL Thymus, Adrenal gland 6 Week(s) Dog Oral 0.125 mg/kg /day LOAEL Adrenal gland 26 Week(s) Dog Oral 2 mg /kg/day LOAEL Adrenal gland, Thymus Reproduction & Developmental Toxicity: (Study TWO. Species. Route. Dose. End Point. Effect) Dexamethasone Embryo / Fetal Development Mouse Subcutaneous 0.15 mg/kg/day LOAEL Teratogenic Embryo / Fetal Development Rat Subcutaneous 1 mg/kg/day NOAEL Teratogenic Embryo / Fetal Development Rabbit intramuscular 0.025 mg/kg/day NOAEL Teratogenic Embryo / Fetal Development Rabbit Subcutaneous 0.02 mg/kg/day LOAEL Maternal Toxicity, Teratogenic renetic Toxicity: (Study BW. Coll TvelOrganism. Result) Dexamethasone Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative In Vitro Mammalian Cell Mutagenicity Rat Negative In Vivo Micronucleus Mouse Equivocal Chromosome Aberration Human Lymphocytes Positive Sister Chromatid Exchange Human Lymphocytes Positive Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

Skin Corrosion/Irritation

Not available.

Serious Eye Damage/Irritation

Not available.

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Respiratory or Skin Sensitization

Not available.

Germ Cell Mutagenicity

Not available.

Carcinogenicity

Not available.

Reproductive Toxicity

Not available.

Routes of Entry

Dermal contact. Eye contact. Inhalation. Ingestion.

Symptoms Related to Exposure

Not available.

Potential Health Effects

Not available.

Target Organ(s) Not available.**Section 12: Ecological Information****Ecotoxicity**

Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Persistence and Degradability

Not available.

Bioaccumulative Potential

Predicted Log P 1.78

Mobility in Soil

Not available.

Other Adverse Effects

Not available.

Section 13: Disposal Considerations**Waste Disposal**

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Disposal of Container

Not available.

Other Considerations

Not available.

Section 14: Transport Information**DOT Classification**

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

Section 15: Regulatory Information**Regulations**

Canada - WHMIS: Classifications WHMIS hazard class: D2a very toxic materials

Other

Not available.

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Section 16: Other Information

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.