



SAFETY DATA SHEET

PRODUCT: Dexamethasone Sodium Phosphate Injection USP 10.0 mg/mL (1 mL)

Section 1: PRODUCT AND COMPANY INFORMATION

54/1, Boodhihal village, Nelamangala, Bangalore, India-562123. PRODUCT NAME: Dexamethasone Sodium Phosphate Injection USP 10.0 mg/mL (1 mL)
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Section 2: HAZARD(S) IDENTIFICATION

EMERGENCY OVERVIEW	
Appearance	A clear colourless solution, free from visible extraneous matter. Filled in amber tubular glass vial plugged with rubber stopper and sealed with flip off aluminium seal.
Potential Acute Health Effects	Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.
Potential Chronic Health Effects:	CARCINOGENIC EFFECTS: Not available. MUTAGENIC EFFECTS: Not available. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Classified Reproductive system/toxin/female [POSSIBLE]. Repeated or prolonged exposure is not known to aggravate medical condition.

Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS

Chemical Name	CAS Number
Dexamethasone Sodium Phosphate	2392-39-4
Sodium Citrate USP Dihydrate	6132-04-3
Citric Acid USP Monohydrate	5949-29-1
Sodium Hydroxide NF	1310-73-2
Water for injection	-

Section 4: FIRST AID MEASURES

Eye Contact	Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention if irritation occurs
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Skin Contact:	Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. Cold water may be used.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Ingestion:	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.

Section 5: FIRE FIGHTING MEASURES

Flammability of the Product:	May be combustible at high temperature.
Products of Combustion:	These products are carbon oxides (CO, CO ₂), halogenated compounds, and phosphates. Some metallic oxides.
Fire Hazards in Presence of Various Substances:	Slightly flammable to flammable in presence of heat. Non-flammable in presence of shocks.
Explosion Hazards in Presence of Various Substances:	Slightly explosive in presence of open flames and sparks. Non-explosive in presence of shocks.
Fire Fighting Media and Instructions:	SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.
Special Remarks on Fire Hazards:	As with most organic solids, fire is possible at elevated temperatures
Special Remarks on Explosion Hazards	Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard.

Section 6: ACCIDENTAL RELEASE MEASURES

Small Spill:	Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.
Large Spill:	Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 7: HANDLING AND STORAGE

Precautions	Keep away from heat. Keep away from sources of ignition. Do not ingest. Do not breathe dust. Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label.
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Storage:	Store as directed by product packaging.
Storage Conditions	20°C – 25°C (68°F – 77°F) [see USP Controlled Room Temperature] Store container in carton until time of use Discard unused portion Protect from light
Specific End Use	Pharmaceutical drug product

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Pharmaceutical drug product	No exposure limits set by NOHSC or ACGIH
Engineering Controls	None under normal operating conditions.
Personal Protection	For good infection control, gloves should be worn when administering an injection.

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information, consult your Occupational Health and Safety Adviser.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance Clear colourless liquid
Odour Odourless
Boiling Point/Melting Point: Not Available
Vapour Pressure Not determined
Vapour Density Not determined
Specific Gravity as for water (approx.)
Flashpoint Not determined
Flammability Limits Not determined
Solubility in Water Aqueous solution.

Section 10: STABILITY AND REACTIVITY

Reactivity:	Not known to be incompatible with other materials.
Chemical Stability:	Stable under recommended storage conditions.
Decomposition Products	Not determined

Possibility of Hazardous Reactions	
Oxidizing Properties:	None
Conditions to Avoid:	Not determined
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	Thermal decomposition products may include carbon monoxide, carbon dioxide, oxides of nitrogen and hydrogen chloride.

Section 11: TOXICOLOGY INFORMATION

Accidental Injection	May cause allergic reactions, nausea, palpitations, and increased blood pressure.
	Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.
Eye	May cause irritation.
Skin	No adverse health effects known.
Inhaled	Not an expected route of exposure.
Chronic Health Effects	No chronic health effects known.
Carcinogen Status:	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.



Section 12: ECOLOGICAL INFORMATION

Eco toxicity

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Aquatic: No data available.

Terrestrial: No data available.

Persistence and Degradability: No data available.

Bio accumulative Potential: No data available.

Mobility in Soil: No data available.

Mobility in Environment: No data available.

Other Adverse Effects: No data available.

Section 13: DISPOSAL CONDITIONS

Waste Disposal:

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: TRANSPORTATION INFORMATION

UN Number None allocated

DG Class None allocated

Subsidiary Risk None allocated

Packing Group None allocated

Hazchem Code None allocated

The following refers to all modes of transportation unless specified below.

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

Section 15: REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Poisons Schedule Number Schedule 4 (S4) – Prescription only medicine



Section 16: OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program

OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System

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