



SAFETY DATA SHEET

PRODUCT: Dexamethasone Sodium Phosphate Injection USP 10.0mg/mL (10 mL)

Section 1: PRODUCT AND COMPANY INFORMATION

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| Wintac Limited 54/1, Boodhihal village, Nelamangala, Bangalore, India-562123. PRODUCT NAME: Dexamethasone Sodium Phosphate Injection USP 10.0mg/mL (10 mL) National Drug Code: 70069-025-01 |
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Section 2: HAZARD(S) IDENTIFICATION

| EMERGENCY OVERVIEW | |
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| Appearance | A clear colorless 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 |
| Benzyl Alcohol | 100-51-6 |
| Sodium Citrate Dihydrate | 6132-04-3 |
| Citric Acid Monohydrate | 5949-29-1 |
| Sodium Hydroxide NF | 1310-73-2 |
| Water for injection | - |

Section 4: FIRST AID MEASURES

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| 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. |
| Eye Contact | Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 to 20 minutes. Cold water may be used. Get medical attention if irritation occurs. |
| Skin Contact: | Wash with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. 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. |

Section 5: FIRE FIGHTING MEASURES

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| 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

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| 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

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| 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. |
| 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

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| 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

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| Appearance: | Clear colourless liquid |
| Decomposition Temperature (°C): | No data available. |
| Evaporation Rate (Gram/s): | No data available |
| Vapour Pressure (kPa): | No data available |
| Vapour Density (g/ml): | No data available |
| Flammability: | Not determined |
| Flash Point (Liquid) (°C): | Not determined |
| Solubility in Water | Aqueous solution. |
| Specific Gravity | As for water (approx.) |
| Boiling Point/Melting Point | Not Available |

Section 10: STABILITY AND REACTIVITY

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| 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

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| 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

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| Eco toxicity | |
| 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

Dispose of material according to Federal, State, and Local regulations.

Section 14: Transportation Information

IATA/ICAO - Not Regulated
IATA Proper shipping Name : N/A
IATA UN/ID No : N/A
IATA Hazard Class : N/A
IATA Packaging Group : N/A
IATA Label : N/A
IMDG - Not Regulated
IMDG Proper shipping Name : N/A
IMDG UN/ID No : N/A
IMDG Hazard Class : N/A
IMDG Flash Point : N/A
IMDG Label : N/A
DOT - Not Regulated
DOT Proper shipping Name : N/A
DOT UN/ID No : N/A
DOT Hazard Class : N/A
DOT Flash Point : N/A
DOT Packing Group : N/A
DOT Label : NA



Section 15: Regulatory Information

FDA Designations: Prescription only medication.
NDC No. 70069-025-01

Section 16: OTHER INFORMATION

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose. Wintac shall not be held liable for any damage resulting from handling or from contact with the above product. Wintac reserves the right to revise this MSDS.

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