

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	Prednisolone Acetate Ophthalmic Suspension USP 1%
Identified uses of the substance or mixture	Pharmaceutical
Manufacturer	Lupin Limited Pithampur (M.P.) – 454 775 INDIA.
Distributor	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

Section 2: Hazard(s) Identification

Classification of the substance or mixture

Carcinogenicity	Not suspected of being a human carcinogen.
Reproductive toxicity	Reproductive toxicity of Category-2 Identified.
Specific target organ toxicity - repeated exposure	No data available
Long-term (chronic) aquatic hazard	No data available

Label elements

Hazard pictograms



Signal word

Danger

Hazard statements

May cause harm to breast-fed children.
Suspected of damaging fertility or the unborn child.

Precautionary statements

IF ON SKIN: Wash with plenty of soap and water.
 If skin irritation occurs: Get medical advice/attention.
 Take off contaminated clothing and wash before reuse.
 If eye irritation persists: Get medical advice/attention.
 Do not handle until all safety precautions have been read and understood.
 Store locked up.
 Dispose of contents/ container to an approved waste disposal plant.
 Wear protective gloves/protective clothing/eye protection/face protection.
 Avoid contact during pregnancy/while nursing.
 Wash face, hands and any exposed skin thoroughly after handling.
 Do not eat, drink or smoke when using this product.

Other hazards

No data available.

Section 3: Composition/Information on Ingredients

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Ingredients	CAS No.	Ingredients	CAS No.
Prednisolone acetate USP	52-21-1	Sodium Bisulfite IH	7631-90-5
Benzalkonium Chloride Solution NF	63449-41-2	Sodium citrate USP	68-04-2
Boric acid NF	10043-35-3	Trisodium Citrate (dihydrate)	68-04-2
Edetate disodium USP (dihydrate)	6381-92-6	Sodium Chloride USP	7647-14-5
Hypromellose USP 2906 (Hydroxypropyl methylcellulose)	9004-65-3	Water for Injection USP	7732-18-5
Polysorbate 80 NF	9005-65-6	-	-

* The exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: First-Aid Measures

General advice

Immediate medical attention is required.

Protection of first aiders

First Aid responders should pay attention to self-protection and use the recommended personal protective equipment when the potential for exposure exists.

Inhaled

Immediate medical attention is required. Remove to fresh air. If not breathing, give artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.

Skin contact

Immediate medical attention is required. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Eye contact

Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. Call a physician immediately.

If swallowed

Do NOT induce vomiting. Call a physician immediately. Never give anything by mouth to an unconscious person. Drink plenty of water.

Section 5: Fire-Fighting Measures

Specific hazards during firefighting	Fire may produce irritating, corrosive and/or toxic gases.
Extinguishing Media	Small Fires: Dry chemical, CO2, water spray or regular foam. Large Fire: Water spray, fog or regular foam. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Special Firefighting Procedures	Structural firefighters' protective clothing will only provide limited protection. Wear positive pressure self-contained breathing apparatus (SCBA).
Hazardous Combustion Products	Fire may produce irritating, corrosive and/or toxic gases.

Section 6: Accidental Release Measures

Personal Precautions	No special controls or personal protection required under conditions of intended use. Use personal protective equipment. Keep people away from and upwind of spill/leak. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.
Environmental Precautions	Prevent further leakage or spillage if safe to do so. Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.
Clean-up Methods	Cover liquid spill with sand, earth or other non-combustible absorbent material. Cover powder spill with plastic sheet or tarp to minimize spreading. Sweep up and shovel into suitable containers for disposal.

Section 7: Handling and Storage

Handling	Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product.
Storage	Keep tightly closed. Store at up to 25°C (77°F). Protect from freezing. Store in an upright position.

Section 8: Exposure Controls/Personal Protection

Engineering Measures/Controls:

Good general ventilation should be used. The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions.

Personal Protective Equipment:

Respiratory: Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

Eye/Face: No eye protection is normally needed during medical administration of this product. Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging. In the event of a spill, appropriate eye protection should be worn. During operations in which dusts of the product may be generated, safety glasses should be considered.

Skin/Body: During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).

Section 9: Physical and Chemical Properties

HOW SUPPLIED

Prednisolone acetate ophthalmic suspension USP, 1% is supplied sterile in opaque white bottle with opaque white nozzle with pink cap as follows:

NDC 70748-332-02: 5 mL in 10 mL bottle
NDC 70748-332-03: 10 mL in 15 mL bottle
NDC 70748-332-04: 15 mL in 15 mL bottle

Odor	No information available
pH	No information available
Melting point/freezing point	No information available
Initial boiling point and boiling range	No information available
Flash points	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability (liquids)	No information available
Upper explosion limit / Upper flammability limit	No information available
Lower explosion limit / Lower flammability limit	No information available
Vapor pressure	No information available
Relative vapor density	No information available
Relative density	No information available
Solubility & Water solubility	No information available
Partition coefficient	No information available
Auto-ignition temperature	No information available
Decomposition temperature	No information available
Viscosity	No information available

Explosive properties No information available

Section 10: Stability and Reactivity

Stability Stable under normal temperatures and pressures
Reactivity Not defined As Reactive substance
Hazardous reactions None under normal processing
Conditions to avoid Aerosol formation to avoid
Hazardous decomposition products None Identified

Section 11: Toxicological Information

Inhalation Acute (Immediate): Under normal conditions of use, no health effects are expected.
Chronic (Delayed): No data available.

Skin Contact Acute (Immediate): Not expected to cause skin irritation.
Chronic (Delayed) : No data available.

Ingestion Acute (Immediate): Oral LD50 - 1680 mg/kg (mouse)
Chronic (Delayed) : No data available.

Eye Contact Acute (Immediate): No data available.
Chronic (Delayed): No data available.

Carcinogenicity Not suspected of being a human carcinogen.

Reproduction toxicity Reproductive development toxicant hazard identified

Section 12: Ecological Information

Eco toxicity Harmful to aquatic life with long lasting effects.
Reactivity None Identified
Hazardous reactions None under normal processing
Conditions to avoid Aerosol formation to be avoided
Hazardous decomposition products None Identified

Section 13: Disposal Considerations

Dispose of contents/containers in accordance with local regulations.

Section 14: Transport 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	:	N/A

Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

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.

Lupin shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this SDS.