SAFET DATA SHEET (SDS)

Difluprednate Ophthalmic Emulsion

- **SECTION – 1: IDENTIFICATION**

Product Name	Difluprednate Ophthalmic Emulsion 0.05% (5 ML) Eye Drop (Plastic Bottle) 5ML
Name of the organization	Amneal Pharmaceuticals Private Limited Parenteral Unit, Ahmedabad 382213, INDIA
Emergency contact numbers	Phone: 91 2714 671600
Therapeutic use	Specified quality tests and assay use only

- **SECTION - 2: HAZARDS IDENTIFICATION**

Contact with skin	May cause an allergic skin reaction. Wash the effected part of the skin with plenty of water. Remove contaminated clothing and wash before use. Obtain medical attention if skin reaction occurs.
Harmful Effect of the drug on Health	May Be Harmful if Ingested or Inhaled in large quantity.
Effects on the Environment	Product is Biodegradable.
Physical & Chemical Hazards	Thermal Decomposition can generate NOx, COx, etc.

This product is Non-hazardous and is governed by FDA Regulation. It is an aqueous emulsion and is not constitute a hazard.

ROUTE OF EXPOSURE

Potential Acute Health Effects:

Hazardous in case of ingestion.

Hazardous in case of skin contact (irritant, permeator), of eye contact (irritant). Slightly hazardous in case of inhalation.

Potential Chronic Health Effects:

CARCINOGENIC EFFECTS: Not available.

MUTAGENIC EFFECTS: Not available.

TERATOGENIC EFFECTS: Not available.

DEVELOPMENTAL TOXICITY: Not available.

The substance is toxic to lungs, mucous membranes. Repeated or prolonged exposure to the substance can produce target organs damage.

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

- **SECTION – 3: COMPOSITION/INFORMATION ON INGREDIENTS**

Usual Chemical Name of the drug used in the bottles			Difluprednate USP
CAS Number for the drug used in the Eye bottles			23674-86-4
Ingredient Contributing to Hazard			
Ingredients of the product	Approximate Percent by Weight (% W/V)	Class	Risk Phrases
Difluprednate USP	0.05 %	Not known	Not known
Route of Entry	Oral, Dermal & Inhalation		

*** These materials are considered non-hazardous under EU, US, and Canadian regulations.**

NOTE: This MSDS is written to address potential worker health and safety issues associated with the handling of the formulated final product, which is an Eye drop, e.g., during the transportation, distribution, and use by medical personnel. For worker health and safety information during the manufacture of Tobramycin and Dexamethasone ophthalmic solution, please refer to the MSDS on each component.

- **SECTION - 4: FIRST-AID MEASURES**

Contact With Skin	May cause an allergic skin reaction. Wash the effected part of the skin with plenty of water. Remove contaminated clothing and wash before use. Obtain medical attention if skin reaction occurs.
Contact With Eyes	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Check for and remove any contact lenses. If pain persists or recurs get medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation	Use proper PPE while handling it. Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Instruction for the physician	In case of inhalation of decomposition products in a fire, symptoms may be delayed. Treat according to symptoms. Keep the victim under medical surveillance.
Protection for first aiders	Use mask. Safety glasses and gloves. Wash the hand with plenty of water.

- **SECTION - 5: FIRE-FIGHTING MEASURES**

Specific hazards	No specific fire or explosion hazard.
Fire extinguishing media	Water, Dry chemical, Carbon Dioxide. For lager fire use water spray or standard foam. Use water delivered as a fine spray to control fire & cool adjacent area. Do not use water jet.
Protection equipment	Fire Fighting with the use of self-content breathing apparatus, appropriate fire suit, boots, helmet, and rubber hand gloves.
Other advice	Cool the containers in the vicinity with sprayed water or move the containers form fire area, if possible.

- **SECTION – 6: ACCIDENTAL RELEASE MEASURES**

Personal precautions	Avoid direct contact. Wear the Personal protective equipment.
Precautions for environmental protection	Keep out of drains; prevent entry into the natural environment.
Cleaning methods	Use appropriate tools to put the spilled liquid in a convenient waste disposal container. Dispose the product as Hazardous waste and Incinerate in an approved facility. Waste must be disposed of in accordance with state and local environmental control regulations.

- **SECTION -7: HANDLING AND STORAGE**

Handling Appropriate technical measures	Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk; evaporate the residue under a fume hood.
Storage Recommended storage conditions	Store at 20° to 25°C (68° to 77°F). [see USP controlled room temperature] in closed container. Protect from light. Keep container dry. Keep in a cool place. Keep container tightly closed. Keep in a cool, well-ventilated place. Combustible materials should be stored away from extreme heat and away from strong oxidizing agents.
Recommended packaging materials	Plastic bottles
Precautions	Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes.

- **SECTION - 8: EXPOSURE CONTROL/PERSONAL PROTECTION**

Technical measures	Handle only with an appropriate nose mask and in a well-ventilated area.
Respiratory protection	Respiratory protection like mask is required.
Hand protection	Gloves
Eye protection	Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 66(EU). Safety glasses
Body and skin protection	Standard working suit
Specific safety protection	Do not drink or eat during handling.
Exposure limits	Not available

- **SECTION - 9: PHYSICAL AND CHEMICAL PROPERTIES**

Size/shape/color or Appearance	White milky aqueous uniform emulsion
Form	Liquid
Odor	Odorless
Water Solubility	Soluble in water
Boiling Point	No data available
Melting Point	No data available
Molecular Weight	No data available
Vapor Pressure	Nil
Specific gravity	No data available
Percent Volite	Nil
Vapor density	Nil
Evaporation	Nil

- **SECTION - 10: STABILITY AND REACTIVITY**

Stability	Material is stable under normal conditions.
Conditions to avoid	Heat and flame.
Materials to avoid	As a precautionary measure, keep away from strong oxidizers
Hazardous decomposition Products	No data available
Incompability	As a precautionary measure, keep away from acids
Hazardous Polymerization	Will not occur

- **SECTION - 11: TOXICOLOGICAL INFORMATION**

Routes of Entry:	Dermal contact. Eye contact. Ingestion.
Toxicity to Animals:	Difluprednate: Acute Oral toxicity (LD50): >4 gm/kg [Rat] Acute Oral toxicity (LD50: >4 gm/kg [Mouse]
Chronic Effects on Humans:	The substance is toxic to lungs, mucous membranes.
Other Toxic Effects on Humans:	Hazardous in case of ingestion. Hazardous in case of skin contact (irritant, permeator). Slightly hazardous in case of inhalation.
Special Remarks on Toxicity to Animals:	Not available.
Special Remarks on Chronic Effects on Humans:	No known significant effects or critical hazards.
Special Remarks on other Toxic Effects on Humans:	No known significant effects or critical hazards.

- **SECTION - 12: ECOLOGICAL INFORMATION**

Persistence / degradation of the drug	The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.
Bioaccumulation	No data available
Aquatic Toxicity	No data available

- **SECTION - 13: DISPOSAL CONSIDERATIONS**

Product disposal	Disposed of in accordance with state and local environmental control regulations.
Disposal of contaminated Packaging & Personal protective equipment	As Above

- **SECTION - 14: TRANSPORT INFORMATION**

Land	RTMD	Class	Not dangerous goods
Rail	RID/ADR	Class	Not dangerous goods
Sea	IMCO/IMDG	Class	Not dangerous goods
Air	OACI/IATA	Class	Not dangerous goods
River	DON/AONR	Class	Not dangerous goods
UN proper shipping name DOT / IATA		Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.	

- **SECTION - 15: REGULATORY INFORMATION**

Eec regulations	US federal regulations CERCLA/SARA Hazardous Substances - Not listed
Federal and State Regulations:	TSCA 8(b) inventory: No products were found.
Hazardous category	Not applicable
Protective Equipment:	Gloves. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate. Splash goggles.
Prevention	P260 - Do not breathe dust/fume/gas/mist/vapors/spray.
Hazard Statement	Not applicable
Safety Phrases	S23 - Do not breathe vapor. S24/25 - Avoid contact with skin and eyes. S37/39 - Wear suitable gloves and eye/face protection.

- **SECTION - 16: OTHER INFORMATION**

Notes:

- ACGIH TLV Limit Value — American Conference of Governmental Industrial Hygienists – Threshold
- CAS — Chemical Abstracts Service Number
- CERCLA Liability Act — US EPA law, Comprehensive Environmental Response, Compensation, and
- DOT — US Department of Transportation Regulations
- EEL — Employee Exposure Limit
- IATA — International Air Transport Association
- LD50 — Dosage producing 50% mortality.
- NIOSH — National Institute for Occupational Safety and Health
- OSHA PEL Limit — US Occupational Safety and Health Administration – Permissible Exposure
- TSCA — Toxic Substance Control Act
- TWA — 8-hour Time Weighted Average
- EC50 = concentration that causes an effect in 50% of test organisms
- LC50 = concentration that is lethal in 50% of test organisms
- NOEC = No Observed Effect Concentration

- **Revision History: -**

Issue date	19-Feb-2024
Revision date	NA
Version #	000
Further information if any,	No

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