SAFETY DATA SHEET

Atropine Sulfate Ophthalmic Solution 1 % (2 mL, 5 mL, 15 mL)

SECTION – 1: IDENTIFICATION

Name of the product	Atropine sulfate ophthalmic Solution 1 % (2 mL, 5 mL, 15 mL) Eye drop packed in Plastic Bottle
Chemical family	Mixture
Name of the organization	Amneal Pharmaceuticals Pvt. Ltd. Plot No. 15,16,17, PHARMEZ- SEZ, Sarkhej-Bavla Highway, Ta. Sanad , Dist. Ahmeddabad- 382220, Gujarat, India.
Emergency contact numbers	Phone : 91 2714 671600
Synonyms for drug used in the Packets	Atropine sulfate ophthalmic Solution 1 %
Therapeutic use	Specified quality tests and assay use only

SECTION - 2: HAZARDS IDENTIFICATION

Hazard Statements	May be harmful if swallowed Harmful to aquatic life. Harmful to aquatic life with long lasting effects.
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.

ROUTE OF EXPOSURE

As Liquid, accidental ingestion; inhalation may exposure

EYE: If discomfort or irritation develops, immediately discontinue product use and contact your eye care professional.

SKIN: Contact with skin can lead to irritation. If skin irritation occurs, discontinue use; remove source of exposure. Flush skin with copious amounts of water. Seek medical attention if irritation persists or signs of toxicity occur.

Inhalation: No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention if cough or other symptoms develop.

Ingestion: If swallowed, get medical help or contact a Poison Control Center immediately.

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 Ophthalmic bottle		Atropine Sulphate	
CAS Number for the drug used in the Bottle		5908-99-6	
Ingredient Contributing to Hazard			
Ingredients of the product	Range/Conc. of drug	Class	Risk Phrases
Atropine sulfate	1 %	Not known	Not known
Benzalkonium Chloride NF	0.01 %	Not known	Not known
NFPA Rating of the drug used in the product	Not classified as per NFPA		
Other ingredient of the product *	Hypromellose 2910 USP , Sodium Phosphate Monobasic (as monohydrate), Sodium Phosphate Dibasic (as anhydrous) etc.		
Route of Entry	Oral, Dermal and Inhale		

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

NOTE: This SDS is written to address potential worker health and safety issues associated with the handling of the formulated final product which is a liquid packed in plastic bottle. e.g., during the transportation, distribution, and use by medical personnel. For worker health and safety information during the manufacture of Atropine sulfate ophthalmic solution, please refer to the SDS on each component.

SECTION - 4: FIRST-AID MEASURES

Contact With Skin	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	If inhaled, remove to fresh air. If breathing is difficult, trained personnel should give oxygen. Get medical attention. Use proper PPE while handling it.
Instruction for the physician	Treat according to symptoms. Keep the victim under medical surveillance.
Protection for first aiders	Use dust mask. Safety glasses and gloves. Wash the hand with plenty of water.

SECTION - 5: FIRE-FIGHTING MEASURES.

Specific hazards	As Liquid, Emits toxic fumes of carbon monoxide and oxides of nitrogen.
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 vessels 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	Sweep up the product, pack in a poly bag, and seal it. 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	Provide the engineering controls. Collect the dust at source of emission/generation.
Storage Recommended storage conditions	Store at 20° to 25°C (68° to 77°F). Keep tightly closed. [see USP controlled room temperature] in closed container. Protect from light.
Recommended packaging materials	Solution packed in plastic bottle
Non-recommended packaging materials	Bare iron drums

SECTION - 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Technical measures	Handle only with an appropriate dust mask and in a well-ventilated area.
Respiratory protection	Respiratory protection like mask is required.
Exposure Limits	Atropine sulfate: 4 µg/m3, 8-hour TWA.
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.

SECTION - 9: PHYSICAL AND CHEMICAL PROPERTIES

Size/shape/colour description of the packets or Appearance	Clear , Colorless Solution
Form	Liquid
Odor	odorless
PH	No data available
Water Solubility	Freely soluble in water
Boiling Point	Not available
Melting Point	As a liquid, not applicable
Molecular Weight	As a mixture, not applicable
Vapor Pressure	Nil
Specific gravity	No data available
Percent Volite	Nil
Vapor density	Nil
Evaporation	Nil
Appearance Color Odor	Clear, Colorless

SECTION - 10: STABILITY AND REACTIVITY

Stability	Material is stable under normal conditions.
Conditions to avoid	Heat and flame. Do not freeze
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

Information on Toxicological

Effects General Information: The information included in this section describes the potential

Hazards of the individual ingredients.

Toxicity of the drug Atropine	Ingestion: Rat Oral LD 50 : 500-600 mg/kg
Inhalation	See Section 02 for details information
Skin contact	May cause mild skin irritation
Eye contact	Non- irritating to the Eyes when use as directed
Carcinogenicity	No data available. Atropine sulphate is not listed by NTP, IARC or OSHA as a carcinogen.
Medical conditions aggravated by exposure	None known

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)	Atropine sulfate: Not classified
Carcinogen Status:	Not classified , None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA
Mutagenicity	Not applicable
Aspiration hazard	Not applicable

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.
Safety Phrases	S23 - Do not breathe vapor. S24 - Avoid contact with skin S37/39 - Wear suitable gloves and eye/face protection
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.
Hazrdous category	Not applicable
Prevention	P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

SECTION - 16: OTHER INFORMATION

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
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	US Occupational Safety and Health Administration – Permissible Exposure Limit
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

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-----End of SDS -----

Bharat Patel - EHS

Digitally signed by Bharat Patel - EHS
DN: cn=Bharat Patel - EHS, o=Amneal Pharmaceuticals Pvt.Ltd, ou=EHS , email=bharat.patel@amnealindia.com, c=IN
Date: 2021.10.29 14:24:29 +05'30'