

*Excelencia en oftálmicos***MATERIAL SAFETY DATA SHEET
ONEDROP**

Date of Issue	Update Date	No. Review	Replaces:
18/Feb/21	Not applicable	HDS-ONEDROP-001	NEW

SECTION 1. Identification of the mixture and the manufacturer

1.1 IDENTIFICATION	
1.1.1 Product Name	
ONEDROP	
1.1.2 Recommended Use and Restrictions on Use:	
<p>ONEDROP is a product made for the temporary relief of eye irritation or burning caused by dry eye.</p> <p>This product is contraindicated in people who have had an allergy to propylene glycol or any of the components of the formula. It is also contraindicated in pregnant or breastfeeding women.</p>	
1.2 MANUFACTURER IDENTIFICATION	
1.2.1 Company Name of the Developer of the SDS	1.2.2 Address
LABORATORIOS SOPHIA S.A. DE C.V.	AV. PASEO DEL NORTE 5255 COL. GUADALAJARA TECHNOLOGY PARK C.P. 45010 ZAPOPAN, JALISCO
1.2.3 Manufacturer	1.2.4 Emergency Telephones
LABORATORIOS SOPHIA S.A. DE C.V.	+ 52 (33) 3001-4200 + 52 (33) 1927-0786 (24-hour Mobile Phone)

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SECTION 2. Hazard(s) identification



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2.1 MIXTURE CLASSIFICATION		
2.1.1 Physical Hazards		
Flammable	Explosiveness	Oxidizing
Not applicable	Not applicable	Not applicable
2.1.2 Health Hazards		
Acute toxicity	Skin irritation	Eye irritation
Not applicable	Not applicable	Not applicable
2.1.3 Other Hazards:		
<p align="center">Reproductive Toxicity</p>  <p align="center">Danger Category 1B H360, P201, P308 +P313</p>		

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SECTION 3. Composition/ information on ingredients

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3.1 RISKY COMPONENTS		
3.1.1 Component Name	3.1.2 Identification No. [CAS]	3.1.3 Concentration in the Mixture
Castor Oil	8001-79-4	≥ 1.0
Boric Acid	10043-35-3	≥ 0.1

SECTION 4. First-aid measures

4.1 DESCRIPTION OF FIRST AID	
4.1.1 Eye contact:	In case of non-therapeutic contact. Wash your eyes under running water for at least 15 minutes, keeping your eyelids open. Cold water can be used. Do not use an eye ointment. Seek medical attention.
4.1.2 Skin contact:	In case of skin contact, remove contaminated clothing. Wash immediately with plenty of water and non-abrasive soap. Take special care to clean any creases, cracks, creases, and groin. Cold water can be used. If irritation persists, seek medical attention.
4.1.3 Ingestion:	In case of accidental ingestion, rinse the mouth with water (only if the person is conscious). Do not induce vomiting. If you are unconscious, seek immediate medical attention.
4.1.4 Inhalation:	Allow rest in a well-ventilated area. Provide fresh air. If discomfort, respiratory distress appears or if in doubt seek immediate medical attention.
4.2 MOST IMPORTANT ACUTE AND CHRONIC SYMPTOMS AND EFFECTS	
<p>The most frequently reported reactions are eye irritation and ineffectiveness, which are typical of artificial tears or lubricants in eye drops. Ophthalmic nanoemulsion with propylene glycol 0.6% may cause blurred vision with instillation.</p> <p>In the case of intake much higher than that contained in the presentation: "It can cause symptoms similar to those presented by alcohol intake."</p>	
4.3 INFORMATION RELEVANT TO IMMEDIATE MEDICAL CARE OR SPECIAL TREATMENT	
Not applicable.	

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SECTION 5. Fire-fighting measures

5.1 MEANS OF EXTINGUISHING

In surrounding fires, use carbon dioxide, dry chemical powder or foam as the case may be. Use water mist to cool materials around the fire.

5.2 SPECIFIC PERSONAL PROTECTIVE EQUIPMENT FOR FIREFIGHTING

Use self-contained breathing equipment and protective clothing to fight surrounding fires.

5.3 SPECIAL PROCEDURE AND PRECAUTIONS DURING FIREFIGHTING

The material is non-flammable, however surrounding fires may occur, use appropriate extinguishing means according to the type of surrounding fire.
The product's container and packaging material can generate toxic gases during a fire

5.4 CONDITIONS LEADING TO ANOTHER SPECIAL HAZARD

It does not contribute to the spread of a fire, however, the product container and packaging material can contribute to an increased risk of fire.

5.5 PRODUCTS OF COMBUSTION THAT ARE HARMFUL TO HEALTH

Carbon oxides (CO, CO₂), nitrogen oxides and sulphur oxides.

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SECTION 6. Accidental release measures

6.1 SPECIAL PROCEDURES AND PRECAUTIONS REQUIRED IN CASES OF LEAKS AND SPILLS

6.1.1	Personal precautions, protective equipment, and emergency procedures.	Wear personal protective equipment, use gloves and safety glasses, ventilate the area.
6.1.2	Environmental precautions	Do not let the product reach the sewer system.
6.1.3	Methods and materials for the containment and clean-up of spills or leaks.	Contain it with an inert, dry material and place it in a suitable container and dispose of it as hazardous waste.

SECTION 7. Handling and storage

7.1 PRECAUTIONS FOR SAFE HANDLING

1. Avoid simultaneous handling of the product with other substances, when these are incompatible.
2. Avoid spillage into the product environment.
3. Wash your hands after using the product.
4. Keep product containers closed.

7.2 SECURE STORAGE CONDITIONS

Store the container tightly closed at room temperature at no more than 30°C.

SECTION 8. Exposure controls/personal protection

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8.1 CONTROL PARAMETERS			
8.1.1 Parameters by component			
Component	VLE-PPT	VLE-CT	VLE-P
Castor Oil	Not Applicable	Not Applicable	Not Applicable
Boric Acid	2 mg/m3	6 mg/m3	6 mg/m3
8.1.2 Other control parameters:			
Not Applicable			
8.2 APPROPRIATE TECHNICAL CONTROLS			
<p>Maintain strict hygiene standards when handling the product and in the places where it is stored. Store in ventilated, cool and dry places. Do not place the product directly on the floor. Read label directions before use.</p>			
8.3 INDIVIDUAL PROTECTION MEASURES			
8.3.1 Personal protective equipment (eyes and face)			
None required under ordinary conditions of use.			
8.3.2 Personal protective equipment (clothing)			
None required under ordinary conditions of use.			
8.3.3 Personal Protective Equipment (Respiratory)			
None required under ordinary conditions of use.			
8.3.4 Personal protective equipment (skin)			
None required under ordinary conditions of use.			
8.3.5 Ventilation. Local extraction system during storage.			
None required under ordinary conditions of use.			
8.3.6 Good hygiene practices			
Maintain strict hygiene standards, do not smoke or eat where the product is stored or handled.			

SECTION 9. Physical and Chemical Properties

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9.1 APPEARANCE (PHYSICAL CONDITION, COLOR, ETC.)	9.11 STEAM PRESSURE
White emulsion	Unavailable
9.2 ODOR	9.12 VAPOUR DENSITY
Odorless	Unavailable
9.3 ODOR THRESHOLD	9.13 RELATIVE DENSITY
Unavailable	1,004 g/mL
9.4 PH	9.14 SOLUBILITY(S)
Between 6.5 to 7.5	Unavailable
9.5 MELTING POINT / FREEZING POINT	9.15 N-OCTANOL/WATER PARTITION COEFFICIENT
Unavailable	Unavailable
9.6 STARTING POINT AND BOILING INTERVAL	9.16 SPONTANEOUS IGNITION TEMPERATURE
Unavailable	Unavailable
9.7 FLASH POINT	9.17 DECOMPOSITION TEMPERATURE
Unavailable	Unavailable
9.8 EVAPORATION RATE	9.18 VISCOSITY
Unavailable	Unavailable
9.9 FLAMMABILITY (SOLID/GAS)	9.19 MOLECULAR WEIGHT
Unavailable	Unavailable
9.10 UPPER/LOWER FLAMMABILITY OR EXPLOSIVENESS LIMIT	
9.10.1 LOWER	9.10.2 SUPERIOR
The product is non-flammable or susceptible to explosion	The product is non-flammable or susceptible to explosion
9.20 OTHER RELEVANT DATA	
Not applicable	

SECTION 10. Stability and reactivity**10.1 REACTIVITY**

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It is a stable substance.
10.2 CHEMICAL STABILITY
It is a substance that is stable under normal ambient conditions of pressure and temperature, and those intended for its handling.
10.3 POSSIBILITY OF DANGEROUS REACTIONS
Not applicable.
10.4 CONDITIONS THAT SHOULD BE AVOIDED
Avoid mixing with substances that react with water. Avoid heat, light, ignition sources.
10.5 INCOMPATIBLE MATERIALS
Strong Acids, Oxidants and Strong Alkalis
10.6 HAZARDOUS DECOMPOSITION PRODUCTS
Unavailable.

SECTION 11. Toxicological information

11.1 PROBABLE ROUTES OF ENTRY	
It can be harmful by inhalation, ingestion and absorption through the skin.	
11.2 EXPOSURE-RELATED SYMPTOMS	
It may cause mild irritation to the skin and gastrointestinal system. It can cause allergic skin reactions. The product in non-therapeutic administration may slightly irritate the conjunctival mucosa and corneal epithelium.	
11.3 IMMEDIATE AND DELAYED EFFECTS	
The most frequently reported reactions are eye irritation and ineffectiveness, which are typical of artificial tears or lubricants in eye drops. Ophthalmic nanoemulsion with propylene glycol 0.6% may cause blurred vision with instillation. Similarly, it has been reported that eye pain, abnormal sensation in the eye, and ocular hyperemia may occasionally occur.	
11.4 NUMERICAL MEASURES OF TOXICITY	
11.4.1 Mean lethal dose:	11.4.2 Mean lethal concentration:
Propylene glycol	LD50 oral rat 20000 mg/kg
	Information Not Available
11.5 INTERACTIVE EFFECTS	

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It has no specific drug interactions.

11.6 SPECIFIC CHEMICAL DATA (IF APPLICABLE)

Not applicable

11.7 MIXTURES

Not applicable

11.8 COMPONENT INFORMATION

Some of the components may cause mild irritation of the respiratory, dermal, and gastrointestinal tracts.

Castor oil: If ingested it can cause colic, and nausea, vomiting, diarrhea and dehydration have occasionally been reported.

Polysorbate 80: If administered in conjunction with amiodarone, hepatotoxicity may occur. Hypersensitivity reactions have occasionally been observed following topical application of preparations containing polysorbates.

Glycerin: Due to the low concentration of the component, side effects are unlikely; however, eye pain, vision changes, redness, or irritation may occasionally occur.

Sodium hyaluronate: May produce transient burning after application

Boric acid: If administered in doses higher than the therapeutic ones, it can cause, depending on the site of application, irritation, redness, vomiting, colic.

Sodium Borate Decahydrate: In case of accidental ingestion it causes nausea, vomiting, diarrhea, abdominal pain, muscle spasms, headache, depression of the central nervous system. Prolonged exposure to the skin causes irritation even a burning sensation

Disodium Edetate Dihydrate: In doses higher than therapeutic ones, it can cause eye irritation. By ingestion: Harmful to health. Not ruled out: Absorption, electrolyte balance disorders

11.9 OTHER INFORMATION

Not applicable

SECTION 12. Ecological information**12.1 TOXICITY**

The product has no toxicity to the environment.

12.2 PERSISTENCE AND DEGRADABILITY

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No data available.
12.3 BIOACCUMULATION POTENTIAL
No data available.
12.4 MOBILITY ON THE GROUND
No data available.
12.5 OTHER ADVERSE EFFECTS
No data available.

SECTION 13. Disposal considerations

13.1 DISPOSAL METHODS
<ul style="list-style-type: none"> - The handling, disposal, and treatment of waste from this product must be done in compliance with federal, state, and local environmental laws. - Do not reuse packaging for another purpose. - Discard immediately after use.

SECTION 14. Transport information

14.1 UN NUMBER
Unavailable.
14.2 OFFICIAL DESIGNATION OF UNITED NATIONS TRANSPORT
Unavailable.
14.3 CLASS(ES) OF TRANSPORT HAZARDS

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Not applicable.
14.4 PACKING/PACKAGING GROUP (IF APPLICABLE)
Not applicable.
14.5 ENVIRONMENTAL RISKS
Avoid spills into the product environment.
14.6 SPECIAL PRECAUTIONS FOR THE USER
1. Avoid simultaneous handling of the product with other substances, when these are incompatible. 2. Wash your hands after using the product.
14.7 BULK TRANSPORTATION (IF APPLICABLE)
Keep product containers closed. Keep the product at room temperature at no more than 30°C.

SECTION 15. Regulatory Information

Not applicable

SECTION 16. Other information, including date of preparation or last revision

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References:

- **Official Mexican Standard-010-STPS-2014** Chemical Agents Contaminating the Work Environment- Recognition, Evaluation and Control
- **Official Mexican Standard-018-STPS-2015** Harmonized System for the Identification and Communication of Hazards and Risks from Hazardous Chemical Substances in the Workplace.
- **Index Merck** 14th edition
- **Globally Harmonized system of Classification and Labeling of Chemicals (GHS)** 4th edition.
- **WHO/EDM/PAR/99.2** Safety Guidelines for the Disposal of Unwanted Pharmaceuticals During and After an Emergency

The information is believed to be correct, but is not exhaustive and will be used for guidance only, which is based on current knowledge of the chemical or mixture and is applicable to appropriate safety precautions for the product.

Laboratorios Sophia S.A. de C. V. does not assume any responsibility for the results obtained in the consequence of a use other than that specified

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