

SAFETY DATA SHEET

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NGHS / English



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1. IDENTIFICATION

Product identifier

Product Name Colirio Ocusan Redness Relief Eye Drops

Other means of identification

Product Code(s) 1554146

Recommended use of the chemical and restrictions on use

Recommended Use Medicinal Liquids (cough medicine, eye drops, ear drops, nasal spray and inhalers)

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Identification DLC Laboratories, Inc.

Address 7008 Marcelle St.
Paramount
CA
90723
US

Telephone Phone: 1-562-602-2184
Fax: 562-602-1931

E-mail info@dlclabs.com

Emergency telephone number

Company Emergency Phone Number Emergency: 1-800-858-3889
CHEMTREC: 1-800-424-9300

2. HAZARDS IDENTIFICATION

Classification



Reproductive toxicity	Category 1B
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Appearance Clear**Physical state** Liquid**Odor** No data available**GHS Label elements, including precautionary statements****Danger****Hazard statements**

May damage fertility or the unborn child

**Precautionary Statements - Prevention**

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information**Unknown acute toxicity** 3.5 % of the mixture consists of ingredient(s) of unknown toxicity

0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

3.5 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

3.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)

3.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)

3.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

3. COMPOSITION/INFORMATION ON INGREDIENTS**Substance**

Not applicable.

Mixture

Chemical name	CAS No.	Weight-%	Hazardous Material	Date HMIRA filed and
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			Information Review Act registry number (HMIRA registry #)	date exemption granted (if applicable)
Tetrahydrozoline HCl	522-48-5	0.05	-	-
Povidone	9003-39-8	1	-	-
Dextran 70	9004-54-0	0.1	-	-
Polyethylene Glycol 400	25322-68-3	1	-	-
Boric Acid	10043-35-3	1-5 *	-	-
Sodium Borate	1303-96-4	0.01-1 *	-	-
Disodium Edetate Hydrate	6381-92-6	0.01-1 *	-	-
Benzalkonium Chloride	63449-41-2	0.01-1 *	-	-
Sodium Chloride	7647-14-5	0.01-1 *	-	-
Water for Injection	7732-18-5	92-97 *	-	-

*The exact percentage of composition is withheld as a trade secret

4. FIRST AID MEASURES

Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water.
Ingestion	Clean mouth with water and drink afterwards plenty of water.

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
Specific hazards arising from the chemical	No information available.
Hazardous Combustion Products	Carbon oxides.
Explosion Data	

Sensitivity to Mechanical Impact NONE.

Sensitivity to Static Discharge NONE.

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Use personal protective equipment as required. Avoid contact with skin, eyes or clothing.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Dam up. Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store locked up.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH	
Boric Acid 10043-35-3	TWA: 2 mg/m ³ inhalable fraction STEL: 6 mg/m ³ inhalable fraction	-		
Sodium Borate 1303-96-4	STEL: 6 mg/m ³ inhalable particulate matter TWA: 2 mg/m ³ inhalable particulate matter	(vacated) TWA: 10 mg/m ³	TWA: 5 mg/m ³	
Chemical name	Alberta	British Columbia	Ontario TWAEV	Quebec
Supplier Trade Secret		TWA: 2 mg/m ³ STEL: 6 mg/m ³	TWA: 2 mg/m ³ STEL: 6 mg/m ³	
Supplier Trade Secret	TWA: 1 mg/m ³ STEL: 3 ppm	TWA: 2 mg/m ³ STEL: 6 mg/m ³	TWA: 2 mg/m ³ STEL: 6 mg/m ³	TWA: 5 mg/m ³

Other Exposure Guidelines Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection No special protective equipment required.

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state Liquid
Appearance Clear
Odor No data available
Color No information available
Odor Threshold No data available

<u>Property</u>	<u>Values</u>	<u>Remarks</u>	<u>Method</u>
pH	6.7		
Melting / freezing point	No data available	None known	
Boiling point / boiling range	No data available	None known	
Flash Point	No data available	None known	
Evaporation Rate	No data available	None known	
Flammability (solid, gas)	No data available	None known	
Flammability Limit in Air		None known	
Upper flammability limit	No data available		
Lower flammability limit	No data available		
Vapor pressure	No data available	None known	
Vapor density	No data available	None known	
Relative density	1		
Water Solubility	Soluble in water		
Solubility(ies)	No data available	None known	
Partition coefficient: n-octanol/water	No data available		
Autoignition temperature	No data available	None known	
Decomposition temperature	No data available	None known	
Kinematic viscosity	No data available	None known	
Dynamic viscosity	No data available	None known	

Other Information

Explosive properties No information available



Oxidizing properties	No information available
Softening Point	No information available
Molecular Weight	No information available
VOC Content (%)	No information available
Liquid Density	No information available
Bulk Density	No information available
Particle Size	No information available
Particle Size Distribution	No information available

10. STABILITY AND REACTIVITY

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of Hazardous Reactions	None under normal processing.
Hazardous Polymerization	Hazardous polymerization does not occur.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous Decomposition Products	Carbon oxides.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	No information available.
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Numerical measures of toxicity

Acute Toxicity

Unknown acute toxicity	3.5 % of the mixture consists of ingredient(s) of unknown toxicity
	0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
	3.5 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
	3.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
	3.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
	3.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Boric Acid	= 2660 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	> 2.03 mg/L (Rat) 4 h
Povidone	= 100 g/kg (Rat)	-	-
Sodium Borate	= 2660 mg/kg (Rat) = 3493 mg/kg (Rat)	> 10000 mg/kg (Rabbit)	> 2.03 mg/L (Rat) 4 h

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical name	ACGIH	IARC	NTP	OSHA
Povidone 9003-39-8	-	Group 3	-	-
Supplier Trade Secret	-	-	-	X

Legend**IARC (International Agency for Research on Cancer)**

Group 3 - Not Classifiable as to Carcinogenicity in Humans

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

X - Present

Reproductive toxicity Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. May damage fertility or the unborn child.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity The environmental impact of this product has not been fully investigated.

Chemical name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Boric Acid 10043-35-3	-	72h LC50: = 1020 mg/L (Carassius auratus)	-	48h EC50: 115 - 153 mg/L

Persistence and Degradability No information available.

Bioaccumulation

Component Information

Chemical name	Log Pow
Boric Acid 10043-35-3	-0.757

Mobility No information available.

Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

California Waste Codes 311

This product contains one or more substances that are listed with the State of California as a hazardous waste.

Chemical name	California Hazardous Waste
Supplier Trade Secret	Toxic
Supplier Trade Secret	Toxic

14. TRANSPORT INFORMATION

DOT
Proper Shipping Name NOT REGULATED
Hazard Class NON-REGULATED
 N/A

TDG Not regulated

MEX Not regulated

ICAO Not regulated

IATA
Proper Shipping Name Not regulated
Hazard Class NON REGULATED
 N/A

IMDG/IMO
Hazard Class Not regulated
 N/A

RID Not regulated

ADR Not regulated

ADN Not regulated



15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

International Inventories

TSCA	Contact supplier for inventory compliance status.
DSL/NDSL	Contact supplier for inventory compliance status.
EINECS/ELINCS	Contact supplier for inventory compliance status.
ENCS	Contact supplier for inventory compliance status.
KECL	Contact supplier for inventory compliance status.
PICCS	Contact supplier for inventory compliance status.
AICS	Contact supplier for inventory compliance status.

Legend

- TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory
- DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List
- EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
- ENCS** - Japan Existing and New Chemical Substances
- KECL** - Korean Existing and Evaluated Chemical Substances
- PICCS** - Philippines Inventory of Chemicals and Chemical Substances
- AICS** - Australian Inventory of Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications. Under the amended regulations at 40 CFR 370, EPCRA 311/312 Tier II reporting for the 2017 calendar year will need to be consistent with updated hazard classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations



California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product may contain substances regulated by state right-to-know regulations.

Chemical name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Boric Acid 10043-35-3	X				X
Supplier Trade Secret	X	X	X		X

16. OTHER INFORMATION

NFPA	Health hazards 1	Flammability 0	Instability 0	Physical and Chemical Properties -
HMIS	Health hazards 1*	Flammability 0	Physical hazards 0	Personal Protection X
<i>Chronic Hazard Star Legend</i>	* = Chronic Health Hazard			

Prepared By Product Stewardship
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Revision Note No information available

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of Safety Data Sheet

