Safety Data Sheet

according to OSHA HCS (29CFR 1910.1200)

Revision: September 25, 2019

1 Identification

· **Product identifier**

· **Trade name: Systane® Ultra Hydration Lubricant Eye drops**
Systane® Hydration PF
· **Product code:** P1516

· **Recommended use and restriction on use**
· **Recommended use:** For the temporary relief of burning and irritation due to dryness of the eye.
· **Restrictions on use:** Contact manufacturer/supplier

· **Details of the supplier of the Safety Data Sheet**
· **Manufacturer/Supplier:**
Alcon Laboratories, Inc.
6201 S. Freeway
Fort Worth, Texas 76134 USA
Tel 1-817-551-4444
E-mail: Safety.Datasheets@Alcon.com

· **Emergency telephone number:**
ChemTel Inc.
(800)255-3924 (North America)
+1 (813)248-0585 (International)

2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified as hazardous according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Not regulated.
· **Hazard pictograms:** Not regulated.
· **Signal word:** Not regulated.
· **Hazard statements:** Not regulated.

· **Other hazards** There are no other hazards not otherwise classified that have been identified.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Components:**

25322-68-3	Polyethylene glycol		<1%
57-55-6	Propylene glycol		<1%
1303-96-4	Disodium tetraborate, decahydrate	Repr. 1B, H360 Eye Irrit. 2A, H319	<1%
10043-35-3	Boric acid	Repr. 1B, H360	<1%

· **Additional information:**
For the listed ingredient(s), the identity and/or exact percentage(s) are being withheld as a trade secret.
For the wording of the listed Hazard Statements, refer to section 16.

4 First-aid measures

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· **Description of first aid measures**
· **After inhalation:** Unlikely route of exposure.
· **After skin contact:**
Wash with soap and water.
Seek medical treatment in case of complaints.
· **After eye contact:**
Product is indicated for ocular usage. In case of persistent or severe irritation after usage, discontinue use and seek medical advice.
· **After swallowing:** Do not induce vomiting; immediately call for medical help.
· **Most important symptoms and effects, both acute and delayed:**
Nausea in case of ingestion.
May cause gastro-intestinal irritation if ingested.
Diarrhea.
Vomiting.
· **Indication of any immediate medical attention and special treatment needed:** Treat symptomatically.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:**
The product is not flammable.
Use fire fighting measures that suit the environment.
· **For safety reasons unsuitable extinguishing agents:** None.
· **Special hazards arising from the substance or mixture** No relevant information available.
· **Advice for firefighters**
· **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Ensure adequate ventilation.
· **Environmental precautions** No special measures required.
· **Methods and material for containment and cleaning up**
Towel or mop up material and collect in a suitable container.
For larger spills, add sawdust, chalk or other inert binding material, then sweep up and discard.
Dispose of the collected material according to regulations.
· **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

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· **Handling**
· **Precautions for safe handling:**
Keep out of reach of children.
Open and handle receptacle with care.

· **Conditions for safe storage, including any incompatibilities**
· **Requirements to be met by storerooms and receptacles:** Store in a cool location.
· **Information about storage in one common storage facility:** No special requirements.
· **Further information about storage conditions:** Storage Temperatures: < 86 ▫F / < 30 ▫C.
· **Specific end use(s)** No relevant information available.

8 Exposure controls/personal protection

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**	
25322-68-3 Polyethylene glycol	
WEEL (USA)	Long-term value: 10 mg/m³ (H); MW>200
57-55-6 Propylene glycol	
WEEL (USA)	Long-term value: 10 mg/m³
EV (Canada)	Long-term value: 155* 10** mg/m³, 50* ppm *vapour and aerosol;**aerosol only
1303-96-4 Disodium tetraborate, decahydrate	
REL (USA)	Long-term value: 5 mg/m³
TLV (USA)	Short-term value: 6* mg/m³ Long-term value: 2* mg/m³ *as inhalable fraction
EL (Canada)	Short-term value: 6 mg/m³ Long-term value: 2 mg/m³
EV (Canada)	Short-term value: 6 mg/m³ Long-term value: 2 mg/m³ inorganic, inhalable
LMPE (Mexico)	Short-term value: 6* mg/m³ Long-term value: 2* mg/m³ A4, *fracción inhalable
10043-35-3 Boric acid	
TLV (USA)	Short-term value: 6* mg/m³ Long-term value: 2* mg/m³ *as inhalable fraction
EL (Canada)	Short-term value: 6 mg/m³ Long-term value: 2 mg/m³
EV (Canada)	Short-term value: 6 mg/m³ Long-term value: 2 mg/m³ inorganic, inhalable

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LMPE (Mexico)	Short-term value: 6* mg/m³ Long-term value: 2* mg/m³ A4;*fracción inhalable

· **Exposure controls**
· **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
Keep away from foodstuffs, beverages and feed.
· **Engineering controls:** No relevant information available.
· **Breathing equipment:** Not required under normal conditions of use.
· **Protection of hands:** Not required under normal conditions of use.
· **Eye protection:** Not required under normal conditions of use.
· **Body protection:** Not required under normal conditions of use.
· **Limitation and supervision of exposure into the environment** No special requirements.
· **Risk management measures** No special requirements.

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **Appearance:**	
Form:	Liquid
Color:	Clear
· **Odor:**	Odorless
· **Odor threshold:**	Not determined.
· **pH-value:**	6.6-7.1
· **Melting point/Melting range:**	Not determined.
· **Boiling point/Boiling range:**	Not determined.
· **Flash point:**	Not applicable.
· **Flammability (solid, gaseous):**	Not applicable.
· **Auto-ignition temperature:**	Not determined.
· **Decomposition temperature:**	Not determined.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Explosion limits**	
Lower:	Not determined.
Upper:	Not determined.
· **Oxidizing properties:**	Non-oxidizing.
· **Vapor pressure:**	Not determined.
· **Density:**	
Relative density:	Not determined.
Vapor density:	Not determined.
Evaporation rate:	Not determined.
· **Solubility in / Miscibility with**	

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Water:	Dispersible.
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity**	
Dynamic:	Not determined.
Kinematic:	Not determined.
· **Other information**	No relevant information available.

10 Stability and reactivity

· **Reactivity:** No relevant information available.
· **Chemical stability:**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used and stored according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid** Excessive heat.
· **Incompatible materials** No relevant information available.
· **Hazardous decomposition products** No dangerous decomposition products known.

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**		
1303-96-4 Disodium tetraborate, decahydrate		
Oral	LD50	2660 mg/kg (rat)
10043-35-3 Boric acid		
Oral	LD50	2660 mg/kg (rat)

· **Primary irritant effect:**
· **On the skin:** No irritant effect.
· **On the eye:** No irritating effect.
· **Sensitization:** No sensitizing effects known.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer):**
None of the ingredients are listed.

· **NTP (National Toxicology Program):**
None of the ingredients are listed.

· **OSHA-Ca (Occupational Safety & Health Administration):**
None of the ingredients are listed.

· **Probable route(s) of exposure:**
Ingestion.
Eye contact.

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Skin contact.
· **Germ cell mutagenicity:** Based on available data, the classification criteria are not met.
· **Carcinogenicity:** Based on available data, the classification criteria are not met.
· **Reproductive toxicity:** Based on available data, the classification criteria are not met.
· **STOT-single exposure:** Based on available data, the classification criteria are not met.
· **STOT-repeated exposure:** Based on available data, the classification criteria are not met.
· **Aspiration hazard:** Based on available data, the classification criteria are not met.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity** No relevant information available.
· **Persistence and degradability** No relevant information available.
· **Bioaccumulative potential:** No relevant information available.
· **Mobility in soil:** No relevant information available.
· **Additional ecological information**
· **General notes:** Generally not hazardous for water.
· **Other adverse effects** No relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation:**
Smaller quantities can be disposed of with household waste.
Small amounts may be diluted with plenty of water and washed away. Dispose of bigger amounts in accordance with Local Authority requirements.
The user of this material has the responsibility to dispose of unused material, residues and containers in compliance with all relevant local, state and federal laws and regulations regarding treatment, storage and disposal for hazardous and nonhazardous wastes.

· **Uncleaned packagings**
· **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· **UN-Number**	
· **DOT, ADR/RID/ADN, IMDG, IATA**	Not regulated.
· **UN proper shipping name**	
· **DOT, ADR/RID/ADN, IMDG, IATA**	Not regulated.
· **Transport hazard class(es)**	
· **DOT, ADR/RID/ADN, IMDG, IATA**	
· **Class**	Not regulated.
· **Packing group**	

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· **DOT, ADR/RID/ADN, IMDG, IATA**	Not regulated.
· **Environmental hazards**	
· **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.

15 Regulatory information

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

· **United States (USA)**

· **SARA**

· **Section 302 (extremely hazardous substances):**

None of the ingredients are listed.

· **Section 355 (extremely hazardous substances):**

None of the ingredients are listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

· **TSCA (Toxic Substances Control Act)**

All ingredients are listed or exempt.

· **Proposition 65 (California)**

· **Chemicals known to cause cancer:**

None of the ingredients are listed.

· **Chemicals known to cause developmental toxicity for females:**

None of the ingredients are listed.

· **Chemicals known to cause developmental toxicity for males:**

None of the ingredients are listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients are listed.

· **EPA (Environmental Protection Agency):**

1303-96-4	Disodium tetraborate, decahydrate	I (oral)
10043-35-3	Boric acid	I (oral)

· **IARC (International Agency for Research on Cancer):**

None of the ingredients are listed.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any

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specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**
H319 Causes serious eye irritation.
H360 May damage fertility or the unborn child.

· **Date of preparation / last revision** September 25, 2019 / -

· **Abbreviations and acronyms:**
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
OSHA: Occupational Safety & Health Administration
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
Repr. 1B: Reproductive toxicity – Category 1B

· **Sources**
Website, European Chemicals Agency (echa.europa.eu)
Website, US EPA Substance Registry Services (ofmpub.epa.gov/sor internet/registry/substreg/home/overview/home.do)
Website, Chemical Abstracts Registry, American Chemical Society (www.cas.org)
Patty's Industrial Hygiene, 6th ed., Rose, Vernon, ed. ISBN: 978-0-470-07488-6
Casarett and Doull's Toxicology: The Basic Science of Poisons, 8th Ed., Klaasen, Curtis D., ed., ISBN: 978-0-07-176923-5.
Safety Data Sheets, Individual Manufacturers

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