Printing date: July 03, 2018 Revision: July 03, 2018

1 Identification

· Product identifier

· Trade name: GenTeal Tears Moderate Preservative Free

Product code: 0065-8063-01

· Recommended use and restriction on use

· Recommended use: Finished product for dry eye relief.

Restrictions on use: No relevant information available.

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

The product is not classified as hazardous according to OSHA GHS regulations within the United States.

- Hazard pictograms: Not regulated.
- · Signal word: Not regulated.
- · Hazard statements: Not regulated.
- · **Precautionary 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:

1303-96-4 Disodium tetraborate, decahydrate

Repr. 1B, H360 <1% Eye Irrit. 2A, H319

· 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

Description of first aid measures

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- · **After inhalation:** Unlikely route of exposure.
- · After skin contact:

Wash with soap and water.

If skin irritation is experienced, consult a doctor.

· After eye contact:

Product is indiciated 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: No relevant information available.
- Indication of any immediate medical attention and special treatment needed:

No relevant information available.

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

- · Handling
- Precautions for safe handling:

Keep out of reach of children.

Open and handle receptacle with care.

Information about protection against explosions and fires: No special measures required.

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(Cont'd. of page 2)

- · 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: Store away from foodstuffs.
- · Specific end use(s) No relevant information available.

8 Exposure controls/personal protection

· Control parameters

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· Components with limit values that require monitoring at the workplace:		
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	

- Exposure controls
- General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

Keep away from foodstuffs, beverages and feed.

Pregnant women should strictly avoid inhalation or ingestion.

- 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.

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		(Cont'd. of page 3)	
· pH-value:	6-8	(00 0. pag)	
• 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	 -		
Water:	Dispersible.		
Partition coefficient (n-octanol/water)	· Partition coefficient (n-octanol/water): Not determined.		
· Viscosity			
Dynamic:	4-15 cps		
Kinematic:	Not determined.		
Other information	No relevant information available.		

10 Stability and reactivity

- · Reactivity: The product is non-reactive under normal conditions of use, storage and transport.
- 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

Under fire conditions only:

Chlorine compounds

11 Toxicological information

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- Information on toxicological effects
- · Acute toxicity: Based on available data, the classification criteria are not met.
- LD/LC50 values that are relevant for classification:

1303-96-4 Disodium tetraborate, decahydrate

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.

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

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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, IMDG, IATA	Not regulated.	
· UN proper shipping name · DOT, ADR, IMDG, IATA	Not regulated.	
· Transport hazard class(es)		
· DOT, ADR, IMDG, IATA · Class	Not regulated.	
· Packing group · DOT, ADR, 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.

· Proposition 65 (California)

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· 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)

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

· Date of preparation / last revision July 03, 2018 / -

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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