

Material Safety Data Sheet

Issuing Date 15-Mar-2011

Revision Date 15-Mar-2011

Revision Number 0

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name TheraTears Preservative Free Lubricant Eye Drops

Recommended Use Artificial Tear / Eye Drop (demulcent)

Supplier Address

Advanced Vision Research
660 Main Street
First Floor, Woburn, MA, 02155
US
Phone: 781-932-8327
Contact: Georgiana Olwell
Contact Phone: 781-939-0117
Emergency Phone: 781-932-8327

Company Emergency Phone Number 781-932-8327

2. HAZARDS IDENTIFICATION

Emergency Overview

Clear liquid with no odor. This product is intended for use as an eye drop.
If you are allergic to any ingredient in this product, do not use.

Appearance Clear, colorless solution

Physical State Liquid, Viscous liquid.

Odor Odorless

Potential Health Effects

Principle Routes of Exposure Eye contact. Skin contact. Inhalation.

Acute Toxicity

Eyes

Non-irritating to the eyes when used as directed.

Skin

Non-irritating to skin and mucous membranes when used as directed.

Inhalation

Not an expected route of exposure. No hazard when used as directed.

Ingestion

Ingestion of amounts greater than individual containers may cause gastrointestinal irritation.

Chronic Effects

No known effect based on information supplied.

Aggravated Medical Conditions

Pre-existing eye disorders.

Environmental Hazard

See Section 12 for additional Ecological Information.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %
Sodium Borate NF	7632-04-4	< 0.1
Potassium Chloride USP	7447-40-7	< 0.1
Sodium Chloride USP	7647-14-5	0.1 - 1
Sodium Phosphate Monobasic USP	7558-80-7	< 0.1
Calcium Chloride USP	10035-04-8	< 0.1
Magnesium Chloride USP	7786-30-3	< 0.1

Sodium Carboxymethylcellulose	9004-32-4	0.1 - 1
Sodium Bicarbonate	144-55-8	0.1 - 1
Boric Acid NF	10043-35-3	0.1 - 1
Water for Injection	7332-18-5	80 - 100
Carbon Dioxide (process only)	124-38-9	0
Nitrogen (process only)	7227-37-9	0

4. FIRST AID MEASURES

Eye Contact	If discomfort or irritation develops, immediate discontinue product use and contact your eye care professional.
Skin Contact	No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.
Inhalation	No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.
Ingestion	No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.
Notes to Physician	Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Flammable Properties	Not flammable.
Flash Point	Not determined.
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Hazardous Combustion Products	Carbon oxides.
Explosion Data	
Sensitivity to Mechanical Impact	No.
Sensitivity to Static Discharge	No.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA	Health Hazard 1	Flammability 0	Stability 0	Physical and Chemical Hazards -
-------------	------------------------	-----------------------	--------------------	--

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Handle in accordance with good industrial hygiene and safety practice.
Environmental Precautions	Refer to protective measures listed in Sections 7 and 8.
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

Handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with eyes.
-----------------	---

Storage Keep container tightly closed. Store at room temperature to maintain product integrity.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Supplier Trade Secret	TWA: 2 mg/m ³ inhalable fraction STEL: 6 mg/m ³ inhalable fraction		
Supplier Trade Secret	STEL = 30000 ppm TWA: 5000 ppm	TWA: 5000 ppm TWA: 9000 mg/m ³ (vacated) TWA: 10000 ppm (vacated) TWA: 18000 mg/m ³ (vacated) STEL: 30000 ppm (vacated) STEL: 54000 mg/m ³	IDLH: 40000 ppm TWA: 5000 ppm TWA: 9000 mg/m ³ STEL: 54000 mg/m ³ STEL: 30000 ppm

ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value. OSHA PEL: Occupational Safety and Health Administration - Permissible Exposure Limits. NIOSH IDLH: Immediately Dangerous to Life or Health.

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

Engineering Measures Showers
Eyewash stations
Ventilation systems

Personal Protective Equipment

Eye/Face Protection

No special protective equipment required.

Skin and Body Protection

No special protective equipment required.

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.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Clear, colorless solution.	Odor	Odorless.
Odor Threshold	No information available.	Physical State	Liquid Viscous liquid
pH	6-9		
Flash Point	No information available.	Autoignition Temperature	No information available
Decomposition Temperature	No information available	Boiling Point/Range	No information available
Melting Point/Range	No information available		
Flammability Limits in Air	No information available	Explosion Limits	No information available
Water Solubility	Fairly soluble	Solubility	No information available
Evaporation Rate	No information available	Vapor Pressure	No data available
Vapor Density	No data available	VOC Content (%)	0.233
Partition Coefficient: n-octanol/water	1.5		

10. STABILITY AND REACTIVITY

Stability	Stable under recommended storage conditions.
Incompatible Products	None known.
Conditions to Avoid	None known.
Hazardous Decomposition Products	Carbon oxides.
Hazardous Polymerization	Hazardous polymerization does not occur.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Product Information Product does not present an acute toxicity hazard based on known or supplied information.

LD50 Oral VALUE 1210109
LD50 Dermal VALUE 266205.2 mg/kg (rat) estimated
LC50 Inhalation (VAPOR) VALUE 3630.715 ml/m³ (vapor) estimated

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Supplier Trade Secret	> 90 mL/kg (Rat)	-	-
Supplier Trade Secret	3 g/kg (Rat)	> 10 g/kg (Rabbit)	> 42 g/m ³ (Rat) 1 h
Supplier Trade Secret	= 27000 mg/kg (Rat)	> 2 g/kg (Rabbit)	> 5800 mg/m ³ (Rat) 4 h
Supplier Trade Secret	= 2660 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	> 0.16 mg/L (Rat) 4 h
Supplier Trade Secret	4220 mg/kg (Rat)	-	-
Supplier Trade Secret	= 2600 mg/kg (Rat)	-	-
Supplier Trade Secret	= 1000 mg/kg (Rat)	= 2630 mg/kg (Rat)	-
Supplier Trade Secret	= 8290 mg/kg (Rat)	> 7940 mg/kg (Rabbit)	-
Supplier Trade Secret	= 2800 mg/kg (Rat)	-	-

Chronic Toxicity

Chronic Toxicity No known effect based on information supplied.

Target Organ Effects None known.

12. ECOLOGICAL INFORMATION

Ecotoxicity

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

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging Dispose of in accordance with local regulations.

California Hazardous Waste Codes 135

This product contains one or more substances that are listed with the State of California as a hazardous waste if discarded prior to inclusion in this formulation.

All disposal methods must be in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations. Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

14. TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated

MEX Not regulated

ICAO Not regulated

IATA Not regulated

IMDG/IMO Not regulated

RID Not regulated

ADR Not regulated

ADN Not regulated

There are no unreasonable risks (health, safety, or property), that this product would pose when transported in commerce. Hazard class definitions (49 CFR, Part 173) are not applicable to this product.

15. REGULATORY INFORMATION

International Inventories

TSCA	Exempt
DSL	Does not Comply
EINECS/ELINCS	Does not Comply
ENCS	Does not Comply
IECSC	Complies
KECL	Does not Comply
PICCS	Complies
AICS	Complies

U.S. Federal Regulations

OSHA

AVR products are subject to their respective Food and Drug Administration (FDA) regulation categories. Accordingly, these products do not require MSDS's as detailed in OSHA regulations 29CFR Part 1910:

...1910.1200(b)(6) "This section does not apply to:"

...1910.1200(b)(6)(vii) "Any drug, as that term is defined in the Federal Food, Drug and Cosmetic Act (21U.S.C. 301 et seq.) when it is in solid, final form for direct administration to the patient (e.g. tablets or pills; drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g. over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (e.g. first aid supplies);"

Any specific product safety concerns are adequately addressed in the FDA-approved package inserts and other labeling within each box of TheraTears® product(s).

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

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

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).

Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs) (see 40 CFR 61)

This product does not contain any substances regulated as hazardous air pollutants (HAPS) under Section 112 of the Clean Air Act Amendments of 1990.

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.

U.S. State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated by state right-to-know regulations.

International Regulations

Mexico - Grade No information available.

Canada

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all the information required by the CPR.

WHMIS Hazard Class

Non-controlled

16. OTHER INFORMATION

Issuing Date 15-Mar-2011

Revision Date 15-Mar-2011

Revision Note No information available

General 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