



**The**  
**HARVARD DRUG GROUP, LLC**  
**MAJOR PHARMACEUTICALS**   
*Rx Brands/Generics & MAJOR Consumer Products*

**MATERIAL SAFETY DATA SHEET**

Issued: **11/15/2010** Prepared by: **Cheryl Perets**  
 Revised: N/A **Generics/Private label**  
 Revision: Original Core No. 069

**1. PRODUCT AND COMPANY INFORMATION**

**Product Name:** Major Opti-Clear Solution 15ml  
**Generic Name:** Tetrahydrozoline HCL Drops 15ml  
**NDC No.** 00904-2992-35

**Legal Category:** Pharmaceutical (OTC) preparation filled inside plastic bottle suitable for dispensing, and overpacked inside a cardboard carton.

**Drug Composition:** Vasoconstrictor

Major Pharmaceuticals  
 31778 Enterprise Drive  
 Livonia, MI 48150

Information: (800) 875-0123 (M-F) 9am-5pm EST  
 Emergency: (800) 875-0123 (M-F) 9am-5pm EST

**2. COMPOSITION/INFORMATION ON INGREDIENTS**

Description	CAS #	TLV (mg/m <sup>3</sup> )	PEL (mg/m <sup>3</sup> )	% Content
Tetrahydrozoline HCL	522-48-5	NE	NE	0.05
Purified Water	NA	NE	NE	≥1

Ingredients <1% - Boric Acid, Sodium Borate, Sodium Chloride, Edetate Disodium, Benzalkonium Chloride

**3. HAZARDS IDENTIFICATION**

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**EMERGENCY OVERVIEW**

Plastic bottle in a cardboard box. Clear, colorless, odorless aqueous solution.

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**Insert Company Name**  
**MSDS: Insert Product Name**

## **POTENTIAL HEALTH HAZARDS**

**Carcinogenicity:** (NTP) No (IARC) No (OSHA) No

**Eye:** May cause irritation and hypersensitivity (anaphylactic) in some individuals. Can induce eye pain or changes in vision, and prolonged use may produce increased redness of the eye.

**Skin:** May cause irritation and hypersensitivity in some individuals.

**Ingestion:** May cause irritation and hypersensitivity in some individuals.

**Inhalation:** May cause irritation and hypersensitivity in some individuals, although this is not likely with a liquid preparation. Vapors produced at controlled room temperature are negligible

**Chronic Effects:** Overuse of this product may induce increased redness of the eye.

**Target Organs:** Eye and respiratory tract.

**Medical Conditions Aggravated by Long Term Exposure:** Hypersensitivity to any of the components of the product. Persons with glaucoma should not use this product without the advice and supervision of a doctor.

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## **4. FIRST AID MEASURES**

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**Eyes:** Rinse immediately with copious amounts of water for at least 20 minutes. Contact a physician.

**Skin:** Remove all contaminated clothing and wash skin with copious amounts of water for at least 20 minutes. Contact physician if skin becomes irritated.

**Ingestion:** Wash out mouth and give plenty of water and bland fluids. Do not give anything to an unconscious person. Contact physician, or contact a Poison Control Center immediately.

**Inhalation:** Remove person to fresh air, and if breathing stops, use artificial respiration. Contact physician.

**Note to Physicians:** Additional details are available on the package insert or in the Physicians Desk Reference.

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## **5. FIRE FIGHTING MEASURES**

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**Flammable Properties:** Flash point: NE Method: NE

**Insert Company Name**  
**MSDS: Insert Product Name**

**Hazardous Products:** Toxic fumes.

**Extinguishing Media:** Dry chemical, carbon dioxide, halon, water fog, and foam on surrounding materials. Water spray will froth if sprayed into the burning material.

**Fire Fighting Instructions:** Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool. Do not spray water into the burning material.

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## **6. ACCIDENTAL RELEASE MEASURES**

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**Large/Small Spills:** Use personal protective equipment. Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste. Dispose of material according to Federal, State and Local regulations.

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## **7. HANDLING AND STORAGE**

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**Handling:** Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment.

**Storage:** Store product upright in original containers with the cap tightly closed at a controlled room temperature 15<sup>0</sup>-30<sup>0</sup> C (59<sup>0</sup>- 86<sup>0</sup> F). **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

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## **8. EXPOSURE CONTROL/PERSONAL PROTECTION**

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**Engineering Controls:** In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process, which will maintain the dust and vapor, levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical material and use current Material Safety Data Sheets.

**Eye Protection:** (29 CFR 1910.133) Recommend goggles or chemical safety glasses.

**Skin Protection:** Thick impermeable gloves and protective clothing.

**Respiratory Protection:** (29 CFR 1910.134) NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw materials.

**Warning:** **Do not use air-purifying respirators in oxygen-depleted environments.** No respiratory protection is required in the clinical or home environment.

**Insert Company Name**  
**MSDS: Insert Product Name**

**Other:** None

**Ventilation:** Recommended

**Contaminated Equipment:** Wash contaminated clothing separately. Wash contaminated equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.

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## 9. CHEMICAL & PHYSICAL PROPERTIES

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Appearance & Odor:	Colorless, odorless, aqueous solution		
Boiling Point:	NE	Evaporation Rate:	NE
Specific Gravity:	1.0	Vapor Density:	NE
Vapor Pressure:	NE	Viscosity:	NE
Water Solubility:	Miscible	Percent Volatile by Volume:	<1

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## 10. STABILITY AND REACTIVITY

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**Chemical Stability:** Stable

**Conditions to avoid:** Extreme heat or cold.

**Incompatibility:** This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.

**Hazardous Decomposition Products:** Toxic fumes.

**Hazardous Polymerization:** Should not occur.

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## 11. TOXICOLOGY

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**Summary of Risks:** Toxicological information refers to raw materials product. Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see MSDS on chemical material

CAS #

522-48-5

**Tetrahydrozoline HCL**

May cause eye, skin, respiratory tract irritation and hypersensitivity (anaphylactic) in some individuals. Overexposure can cause headache, drowsiness, weakness, tremors, light headedness, insomnia and heart palpitations. Repeated or prolonged exposure may cause congestion.

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## 12. ECOLOGICAL INFORMATION

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**Insert Company Name**  
**MSDS: Insert Product Name**

**Chemical Fate Information:** Product administered to patients presents a negligible impact on the environment.

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### **13. DISPOAL INFORMATION**

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**Dispose of material according to Federal, State, and Local regulations.** The method typically used is incineration.

**EPA Designations:** RCRA Hazardous Waste: Not Listed

**SARA Title III:** Not Listed

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### **14. TRANSPORTATION INFORMATION**

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**Transportation Data:** Not classified as hazardous by DOT regulations.

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### **15. REGULATORY INFORMATION**

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**DOT Designations:** Not classified as hazardous by DOT regulations.

**EPA Designations:** RCRA Hazardous Waste  
(40 CFR 261.33) Not Listed

**FDA Designations:** OTC medication.  
NDC No. **Insert Number**

**OSHA Designations:** (29 CFR 1910.1000, Table Z)  
Not Listed

**SARA Title III:** Not listed under Section 313 of Toxic Release Reporting.

**CALIFORNIA PROPOSITION 65:** Not Listed

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### **16. OTHER INFORMATION**

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None

The information contained herein is furnished without warranty of any kind. The above information is believed to be correct but does not purport to be all-inclusive and should be used only as a guide. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers.

NE- Not Established

< - Less Than

> - Greater Than