BAUSCH & LOMB

Pharmaceutical Division

MATERIAL SAFETY DATA SHEET

Issued:	12/20/01	Prepared by:	Gary Wong
Revised:	NA		Manager EHS
Revision:	Original	Core No. 394	

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: REV—EYES®
Generic Name: Dapiprazole Hydrochloride Ophthmalic Solution 0.5%
NDC No. 24208-394-07 (25 mg)

Legal Category: Prescription only medicine, filled in bottle supplied with vial of diluent, dropper for dispensing, and overpacked inside a cardboard carton.

Drug Composition: Antiglaucoma; miotic

BAUSCH & LOMB PHARMACEUTICALS, INC.
8500 Hidden River Parkway
Tampa, FL 33637
Information: (800) 323-0000 (M-F) 8am-5pm EST
Emergency: (800) 227-1427 24 hrs

2. COMPOSITION/INFORMATION ON INGREDIENTS

Description	CAS #	TLV (mg/m^3)	PEL(mg/m^3)	% Content
Dapiprazole Hydrochloride	72822-13-0	35 mcg/m^3 eye, (REL, Abbott)		0.5
Mannitol		10 mg/m^3 total 5 mg/m^3 respirable	15 mg/m^3 total 5 mg/m^3 respirable	2.0

Ingredients <1% - Sodium Chloride, Hydroxypropyl Methylcellulose, Edetate Sodium, Sodium Phosphate dibasic, Sodium Phosphate monobasic, Water, Benzalkonium Chloride

3. HAZARDS IDENTIFICATION

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EMERGENCY OVERVIEW

Contact with eyes may cause pupil constriction. Target organs are eyes and cardiovascular system.

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POTENTIAL HEALTH HAZARDS

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

Eye: No data

Skin: No data

Ingestion: No data

Inhalation: No data

Chronic Effects:

Target Organs:

Medical Conditions Aggravated by Long Term Exposure: Data suggest hypersensitivity to dapiprazole, ocular lesions, such as acute iritis, and cardiovascular disease.

Contraindications: Miotics are contraindicated where constriction is undesirable; such as acute iritis, and in those subjects showing hypersensitivity to any component of this preparation.

4. FIRST AID MEASURES

Eyes: Remove from source of exposure. Flush with copious amounts of water for at least 20 minutes. If irritation persists or signs of toxicity occur, seek medical attention. No known antidote. Provide symptomatic/supportive care as necessary. Contact a physician.

Skin: Remove from source of exposure. Flush with copious amounts of water for at least 20 minutes. If irritation persists or signs of toxicity occur, seek medical attention. No known antidote. Provide symptomatic/supportive care as necessary. Contact physician if skin becomes irritated.

Ingestion: Wash out mouth and give plenty of water and bland fluids. Contact a physician.

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

Note to Physicians: Carcinogenesis, Mutagenesis, Impairment of Fertility: Dapiprazole hydrochloride has been shown to significantly increase the incidence of liver tumors in rats after continuous dietary administration for 104 weeks. This effect was found only in male rats treated with the highest dose administered in the study, i.e., 300 mg/kg/day, (80,000 times the human dose) and was not observed in male and female rats at doses of 30 and 100 mg/kg/day and female rats at doses of 300 mg/kg/day. Negative results have been reported on the mutagenicity and impairment of fertility studies with dapiprazole hydrochloride.
Pregnancy Category B. Reproduction studies have been performed in rats and rabbits at doses up to 128,000 (rat) and 27,000 (rabbit) times the human ophthalmic dose and revealed no evidence of impaired fertility or harm to the fetus due to dapiprazole hydrochloride. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when dapiprazole hydrochloride ophthalmic solution is administered to a nursing woman.

For Topical Ophthalmic Use Only. NOT FOR INJECTION.

Additional details are available on the package insert or in the Physicians Desk Reference.

5. FIRE FIGHTING MEASURES

Flammable Properties: Flash point: NE Method: NE

Flammable Limits: Lower Flammable Limit: NE Upper Flammable Limit: NE

Autoignition Temperature: NE

Hazardous Products: Emits toxic fumes.

Extinguishing Media: Dry chemical, carbon dioxide, halon, water spray or fog, and foam on surrounding materials.

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.

6. ACCIDENTAL RELEASE MEASURES

Large/Small Spills: Notify your supervisor immediately. Minimize contact with spilled material. Keep other personnel away from the clean up area. Wear appropriate respiratory protection. Wear approved respirator and chemically compatible gloves. Use personal protective equipment. (Refer to Section 8) Squeegee, scoop, absorb or use a vacuum to clean up spill. Clean area with an alkaline cleaner/detergent. Dispose of waste material in accordance with Federal, State and Local regulations.

While not a RCRA hazardous waste, material should be disposed of according to Federal, State and Local regulations. Incineration is the preferred disposal method.

7. HANDLING AND STORAGE

This material should be handled and stored per label and other instructions to ensure product integrity.

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 15^0-30^0 C (59^0- 86^0 F). **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

8. EXPOSURE CONTROL/PERSONAL PROTECTION

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.

Other: None

Ventilation: Recommended. Provide adequate local exhaust ventilation.

Hygienic Practices: Train employees concerning hazards and precautions. Wash hands and forearms after each use and use recommended personal protective equipment while handling.

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

9. CHEMICAL & PHYSICAL PROPERTIES

Appearance & Odor:

Boiling Point:	NE	Evaporation Rate:	NE
Melting Point:	NE	Vapor Density:	NE
Vapor Pressure:	NE	Specific Gravity:	NE
Water Solubility:	Soluble	Percent Volatile by Volume:	<1

10. STABILITY AND REACTIVITY

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: Emits toxic fumes.

Hazardous Polymerization: Should not occur.

11. TOXICOLOGY INFORMATION

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 #

72822-13-0 **Dappiprazole Hydrochloride**

In controlled studies the most frequent reaction to dapiprazole was conjunctival injection lasting 20 minutes in over 80% of patients. Burning on instillation of dapiprazole hydrochloride ophthalmic solution was reported in approximately half of all patients. Reactions occurring in 10% to 40% of patients included ptosis, lid erythema, lid edema, chemosis, itching, punctate keratitis, corneal edema, browache, photophobia and headaches. Other reactions reported less frequently included dryness of eyes, tearing and blurring of vision.

TOXICITY:
Oral toxicity: N/D. LD50 for Dapiprazole HCl = 1189—2100 mg/kg in mice, rats and rabbits.

Dermal toxicity: N/D

Inhalation toxicity: N/D

Corrosiveness: N/D

Dermal irritation: N/D

Ocular irritation: N/D

Dermal sensitization: N/D

Special target organ effects: N/D. In clinical use dapiprazole hydrochloride is an alpha—adrenergic blocking drug that causes the pupil of the eye to become smaller, can reduce blood pressure and can reverse the effects of opiate and alcohol withdrawal.

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL INFORMATION

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

14. TRANSPORTATION INFORMATION

Transportation Data: Not classified as hazardous by DOT regulations.

15. REGULATORY INFORMATION

DOT Designations: Not classified as hazardous by DOT regulations.

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

FDA Designations: Prescription only medication.
NDC No. 24208-07 (25 mg)

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

16. OTHER INFORMATION

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
N/D – Not Determined
< - Less Than
> - Greater Than