

MATERIAL SAFETY DATA INFORMATION

3-FEB-1993

***** SECTION I *****

MANUFACTURER/SOURCE OF INFORMATION: ALCON LABORATORIES, INC.

EMERGENCY TEL: 817-551-4444

ADDRESS: 6201 S. FREEWAY, FT. WORTH, TX 76134

CHEMICAL NAME AND SYNONYMS:

BETOPTIC 0.5%, 2.5 ML, 5 ML, 10 ML, 15 ML;

CAS NO.: AP0000076

PRODUCT CODE: NDC 0065-0245-20;-05;-10;-15

PMA/NDA NO.: 19-270

CERCLA HAZARD RATINGS (SCALE 0-3):

HEALTH-N/A

FIRE-N/A

REACTIVITY-N/A

PERSISTENCE-N/A

***** SECTION II (COMPONENTS AND CONTAMINANTS) *****

PERCENTAGE: 0.56% + 2% EXC

0.8%

0.01%

0.01% + 5% EXC

q.s.

COMPONENT: BETAXOLOL HYDROCHLORIDE

SODIUM CHLORIDE, USP

EDETATE DISODIUM

BENZALKONIUM CHLORIDE

HYDROCHLORIC ACID AND/OR SODIUM

HYDROXIDE TO ADJUST pH

PURIFIED WATER

***** SECTION III (PHYSICAL DATA) *****

HAZARD DESCRIPTION: CLEAR AQUEOUS SOLUTION.

BOILING POINT: N/A

MELTING POINT: N/A

SPECIFIC GRAVITY: N/A

VAPOR PRESSURE: N/A

EVAPORATION RATE: N/A

SOLUBILITY IN WATER: MISCIBLE

VAPOR DENSITY: N/A

***** SECTION IV (FIRE AND EXPLOSION HAZARD DATA) *****

FIRE AND EXPLOSION HAZARD: NONE

FLASH POINT: N/A

UPPER EXPLOSION LIMIT: N/A

LOWER EXPLOSION LIMIT: N/A

FIREFIGHTING MEDIA: USE EXTINGUISHING MEDIA APPROPRIATE FOR THE SURROUNDING FIRE CONDITIONS.

FIREFIGHTING: WEAR SELF-CONTAINED BREATHING APPARATUS AND PROTECTIVE CLOTHING.

***** SECTION V (HEALTH EFFECTS AND FIRST AID) *****

*TOXICITY: THE MAJOR ACTIVE INGREDIENT, BETAXOLOL HCl, IS A CARDIOSELECTIVE BETA-1-ADRENERGIC RECEPTOR BLOCKING AGENT. EACH ML OF BETOPTIC CONTAINS 5.6 MG BETAXOLOL HCl. ALTHOUGH TOPICAL OPHTHALMIC ADMINISTRATION OF BETOPTIC HAS HAD LITTLE OR NO EFFECT ON HEART RATE OR BLOOD PRESSURE, ORALLY ADMINISTERED BETA-ADRENERGIC BLOCKING AGENTS ARE KNOWN TO REDUCE CARDIAC OUTPUT. CAUTION SHOULD BE

OBSERVED IN TREATING PATIENTS WITH A HISTORY OF CARDIAC DISEASE.

TOPICAL OR PARENTERAL CONTACT WITH HIGH CONCENTRATIONS OF SOME OF THE COMPONENTS OF THIS OPHTHALMIC FORMULATION ARE KNOWN TO PRODUCE HYPERSENSITIVITY REACTIONS IN A SMALL NUMBER OF PERSONS. AS THE CONCENTRATION OF THESE COMPONENTS IS RELATIVELY SMALL IN THE FINISHED PRODUCT, THIS FORMULATION SHOULD NOT PRESENT A SIGNIFICANT CONTACT HAZARD TO HUMANS.

PRECAUTIONS TO CONSIDER: PERSONS DEVELOPING HYPERSENSITIVITY (ANAPHYLACTIC) REACTIONS MUST RECEIVE IMMEDIATE MEDICAL ATTENTION.

AS A GENERAL RULE, INDIVIDUALS WORKING WITH CHEMICALS SHOULD CONSIDER ALL CHEMICALS TO BE POTENTIALLY HAZARDOUS EVEN IF THEIR INDIVIDUAL HAZARDS MAY BE UNCHARACTERIZED OR UNKNOWN.

CARCINOGENICITY: LIFE-TIME STUDIES WITH THE ACTIVE INGREDIENT HAVE BEEN CONDUCTED IN MICE AND RATS AND DEMONSTRATED NO CARCINOGENIC EFFECT.

INHALATION--

.ACUTE EXPOSURE: SOME COMPONENTS OF THIS PRODUCT MAY CAUSE IRRITATION TO THE RESPIRATORY TRACT SHOULD INSUFFLATION OF PRODUCT OCCUR.

.CHRONIC EXPOSURE: SEE ACUTE EXPOSURE

.FIRST AID: REMOVE TO FRESH AIR. IF NOT BREATHING, PERFORM ARTIFICIAL RESUSCITATION. IF BREATHING IS DIFFICULT, GIVE OXYGEN. OBTAIN APPROPRIATE MEDICAL ATTENTION.

SKIN CONTACT--

.ACUTE EXPOSURE: THIS PRODUCT CONFORMS TO FDA REGULATIONS AND GUIDELINES FOR AN OPHTHALMIC FORMULATION AND THUS IT IS NOT EXPECTED TO PRODUCE DERMAL IRRITATION. MINIMAL DERMAL IRRITATION MAY OCCUR UPON PROLONGED OR REPEATED DERMAL EXPOSURE TO SENSITIVE INDIVIDUALS.

CHRONIC EXPOSURE: SEE ACUTE EXPOSURE

.FIRST AID: IF IRRITATION OCCURS, IMMEDIATELY FLUSH SKIN WITH COPIOUS AMOUNTS OF WATER. IN THE EVENT OF ANY UNDESIRABLE EFFECTS, OBTAIN APPROPRIATE MEDICAL ATTENTION.

EYE CONTACT--

.ACUTE EXPOSURE: THIS PRODUCT CONFORMS TO FDA REGULATIONS AND GUIDELINES FOR AN OPHTHALMIC FORMULATION THAT HAS BEEN EXTENSIVELY TESTED AND DEMONSTRATED TO BE SAFE FOR USE IN THE EYE. MINIMAL OCULAR IRRITATION MAY OCCUR FOLLOWING AN EXCESSIVE TOPICAL OCULAR EXPOSURE BEYOND THERAPEUTIC LEVELS SUCH AS IN PRODUCT ABUSE OR IN AN INDUSTRIAL ACCIDENT. DISCOMFORT OF SHORT DURATION HAS BEEN REPORTED IN SOME PATIENTS RECEIVING THE DRUG AND RARE INSTANCES OF DECREASED CORNEAL SENSITIVITY, CORNEAL PUNCTATE STAINING, KERATITIS, UNEQUAL PUPIL SIZE (ANISOCORIA) AND PHOTOPHOBIA HAVE BEEN REPORTED.

.CHRONIC EXPOSURE: SEE ACUTE EXPOSURE

.FIRST AID: IF IRRITATION OCCURS, IMMEDIATELY FLUSH EYES WITH COPIOUS AMOUNTS OF WATER. IN THE EVENT OF ANY UNDESIRABLE EFFECTS, OBTAIN APPROPRIATE MEDICAL ATTENTION.

INGESTION--

.ACUTE EXPOSURE: THE CONCENTRATION OF ACTIVE OR POTENTIALLY TOXIC MATERIAL

AVAILABLE IN ONE BOTTLE OF THIS PRODUCT SHOULD NOT PRODUCE A SIGNIFICANT ORAL HAZARD SHOULD ACCIDENTAL OR INTENTIONAL INGESTION OCCUR. THE ORAL LD-50 OF THE DRUG RANGED FROM 350-920 MG/KG IN MICE AND 860-1050 MG/KG IN RATS. THE SYMPTOMS WHICH MIGHT BE EXPECTED FROM AN OVERDOSE OR CHRONIC EXPOSURE OF A SYSTEMICALLY ADMINISTERED BETA BLOCKER AGENT ARE BRADYCARDIA, HYPOTENSION, AND ACUTE CARDIAC FAILURE.

.CHRONIC EXPOSURE: SEE ACUTE EXPOSURE

.FIRST AID: WASH OUT MOUTH WITH WATER AND INDUCE VOMITING. IN THE EVENT OF ANY UNTOWARD EVENTS, OBTAIN APPROPRIATE MEDICAL ATTENTION.

***** SECTION VI (REACTIVITY DATA) *****

REACTIVITY: STABLE

INCOMPATIBILITIES: NONE

DECOMPOSITION: STABLE

POLYMERIZATION: WILL NOT OCCUR

*CONDITION TO AVOID: MATERIAL IS STABLE FROM SAFETY POINT OF VIEW.

***** SECTION VII (SPILL OR LEAK PROCEDURES) *****

SPILL: WEAR APPROVED RESPIRATOR AND CHEMICALLY COMPATIBLE GLOVES. VACUUM OR SWEEP UP SPILLAGE. AVOID DUST. PLACE SPILLAGE IN APPROPRIATE CONTAINER FOR WASTE DISPOSAL. WASH CONTAMINATED CLOTHING BEFORE REUSE. VENTILATE AREA AND WASH SPILL SITE.

DISPOSAL: DISPOSE IN ACCORDANCE WITH ALL APPLICABLE FEDERAL, STATE AND LOCAL ENVIRONMENTAL REGULATIONS. THIS PRODUCT DOES NOT MEET THE DEFINITION OF HAZARDOUS WASTE AS DEFINED IN 40CFR, PART 261.11.

***** SECTION VIII (SPECIAL PROTECTION INFORMATION) *****

THE FOLLOWING INFORMATION ASSUMES LARGE QUANTITIES OF THE PRODUCT SUCH AS MIGHT BE ENCOUNTERED IN WAREHOUSE STORAGE OR AN INDUSTRIAL ACCIDENT.

VENTILATION: USE GENERAL OR LOCAL EXHAUST

FIREFIGHTING: SELF-CONTAINED BREATHING APPARATUS SHOULD BE USED WHEN FIGHTING FIRES INVOLVING A CHEMICAL.

CLOTHING: APPROPRIATE LABORATORY APPAREL, PROTECT EXPOSED SKIN

GLOVES: RUBBER

EYE PROTECTION: SAFETY GOGGLES

RESPIRATORY PROTECTION: NIOSH/OSHA-APPROVED RESPIRATOR

***** SECTION IX (STORAGE AND HANDLING PRECAUTIONS) *****

SPECIAL PRECAUTIONS: STORE IN TIGHT CONTAINER AS DEFINED IN THE UNITED STATES PHARMACOPEIA. THIS MATERIAL SHOULD BE HANDLED AND STORED PER LABEL AND OTHER INSTRUCTIONS TO ENSURE PRODUCT INTEGRITY.

OTHER PRECAUTIONS: AVOID CONTACT WITH EYES, SKIN OR CLOTHING. AVOID
BREATHING DUST OR MIST. USE WITH ADEQUATE DUST CONTROL.
WASH THOROUGHLY AFTER HANDLING. DO NOT PERMIT EATING,
DRINKING OR SMOKING NEAR MATERIAL.

***** SECTION X (TRANSPORTATION AND SHIPPING INFORMATION) *****

THIS PRODUCT DOES NOT POSE AN UNREASONABLE RISK TO HEALTH AND SAFETY OR
PROPERTY WHEN TRANSPORTED IN COMMERCE. THE HAZARD CLASS DEFINITIONS OF
49CFR, PART 173 ARE NOT APPLICABLE TO THIS PRODUCT.

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.

APPROVED:
R&D: R.P./E.D./J.H.
T.K. 5/23/89

REVISION 2:
R&D: J.H.

DATE: 2/2/93

DATE: 10/14/87