

MATERIAL SAFETY DATA INFORMATION

15-FEB-1993

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

MANUFACTURER/SOURCE OF INFORMATION: ALCON LABORATORIES, INC.*
EMERGENCY TEL: 817-551-4444
ADDRESS: 6201 SOUTH FREEWAY, FT. WORTH, TEXAS 76134

CHEMICAL NAME AND SYNONYMS:

IOPIDINE; APRACLONIDINE HYDROCHLORIC OPHTHALMIC SOLUTION;

CAS NO.: AP0000316

PRODUCT CODE: NDC 0065-0660-10
0065-0660-25
0065-0660-30

PMA/NDA NO: 19-779

CERCLA HAZARD RATINGS (SCALE 0-3):

HEALTH-N/A	FIRE-N/A	REACTIVITY-N/A	PERSISTENCE-N/A
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***** SECTION II (COMPONENTS AND CONTAMINANTS) *****

PERCENTAGE: 1.15%	COMPONENT: APRACLONIDINE HYDROCHLORIDE
0.07%	SODIUM ACETATE (TRIHYDRATE)
0.6%	SODIUM CHLORIDE
0.01%	BENZALKONIUM CHLORIDE SOLUTION (10%)
ADJ PH	HYDROCHLORIC ACID
ADJ PH	SODIUM HYDROXIDE
Q.S.	PURIFIED WATER

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

HAZARD DESCRIPTION: CLEAR, COLORLESS TO LIGHT YELLOW LIQUID.

BOILING POINT: N/A MELTING POINT: N/A

SPECIFIC GRAVITY: 1.0 VAPOR PRESSURE: N/A

EVAPORATION RATE: N/A SOLUBILITY IN WATER: ALL COMPONENTS ARE
WATER SOLUBLE

VAPOR DENSITY: N/A

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

FIRE AND EXPLOSION HAZARD: THIS MATERIAL SHOULD NOT PRESENT A FIRE OR
EXPLOSION HAZARD.

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.

TOXIC GASES PRODUCED: CARBON OXIDES, NITROGEN OXIDES PRODUCED ON DECOMPOSITION.

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

*TOXICITY:

THE ORAL LD₅₀ FOR APRACLONIDINE IN RATS IS 63.9 MG/KG AND IN MICE IS 5.04 MG/KG. PRIMATES RECEIVING THIS COMPOUND ORALLY (SINGLE DOSE) AT UP TO 55 MG/KG DISPLAYED SIGNS OF TOXICITY BUT RECOVERED TO NORMAL WITHIN 5-7 DAYS. ONE CONTAINER OF IOPIDINE CONTAINS NOT MORE THAN 2.875 MG OF APRACLONIDINE. MANIFESTATIONS OF SYSTEMIC TOXICITY SEEN ON OCULAR ADMINISTRATION OF IOPIDINE INCLUDE DRY MOUTH AND HEADACHE.

REPRODUCTION, TERATOLOGY AND PERI- AND POSTNATAL STUDIES HAVE BEEN CONDUCTED WITH ORALLY ADMINISTERED APRACLONIDINE HYDROCHLORIDE IN RATS AND/OR RABBITS. THIS COMPOUND WAS NOT TERATOGENIC AND DID NOT AFFECT FERTILITY OR REPRODUCTIVE CAPACITY. FETO/EMBRYOTOXICITY WAS PRESENT AT DOSES CAUSING MATERNAL TOXICITY. REDUCED OFFSPRING VIABILITY AND WEIGHT GAIN WERE SEEN DURING THE LACTATION PERIOD IN RATS AT MATERNALLY TOXIC DOSES.

CARCINOGENICITY: LIFETIME ADMINISTRATION OF APRACLONIDINE TO RATS AND MICE DID NOT SHOW CARCINOGENIC POTENTIAL. THIS COMPOUND IS NOT LISTED AS A CARCINOGEN BY NTP, OSHA OR IARC.

INHALATION--

- .ACUTE EXPOSURE: INSUFFLATION MAY CAUSE NASAL DRYNESS, BURNING, IRRITATION OF THE NOSE AND THROAT.
- .CHRONIC EXPOSURE: POSSIBLE HYPERSENSITIZATION.
- .FIRST AID: REMOVE FROM EXPOSURE. TREAT SYMPTOMATICALLY.

SKIN CONTACT--

- .ACUTE EXPOSURE: MAY CAUSE IRRITATION.
- .CHRONIC EXPOSURE: REPEATED EXPOSURE MAY RESULT IN DELAYED HYPERSENSITIVITY IN SUSCEPTIBLE INDIVIDUALS.
- .FIRST AID: REMOVE CONTAMINATED CLOTHING AND FLUSH SKIN WITH COPIOUS AMOUNTS OF WATER FOR AT LEAST 15 MINUTES.

EYE CONTACT--

- .ACUTE EXPOSURE: MAY CAUSE TRANSIENT IRRITATION, CONJUNCTIVAL BLANCHING, MYDRIASIS.
- .CHRONIC EXPOSURE: REPEATED EXPOSURE MAY RESULT IN DELAYED HYPERSENSITIVITY IN SUSCEPTIBLE INDIVIDUALS. TOPICAL SOLUTION OF UP TO 1.5% ADMINISTERED IN ANIMALS THREE TIMES A DAY DID NOT RESULT IN SIGNIFICANT OCULAR OR SYSTEMIC EFFECTS.
- .FIRST AID: IMMEDIATELY FLUSH EYES WITH COPIOUS AMOUNTS OF WATER FOR AT LEAST 15 MINUTES.

INGESTION--

- .ACUTE EXPOSURE: APRACLONIDINE MAY CAUSE STOMACH DISCOMFORT, DIARRHEA, EMESIS, ABDOMINAL PAIN. SYSTEMIC EXPOSURE MAY CAUSE CARDIOVASCULAR EFFECTS, DROWSINESS, SEDATION, CONSTIPATION, DIZZINESS, HEADACHE AND FATIGUE.
- .CHRONIC EXPOSURE: POSSIBLE HYPERSENSITIZATION AND OTHER EFFECTS AS ABOVE.
- .FIRST AID: DISCONTINUE EXPOSURE. TREAT SYMPTOMATICALLY.

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

REACTIVITY: STABLE

INCOMPATIBILITIES: NONE OTHER THAN WHAT WATER ALONE WOULD PRODUCE.

DECOMPOSITION: WHEN HEATED TO DECOMPOSITION, MATERIAL EMITS TOXIC FUMES.

POLYMERIZATION: WILL NOT OCCUR

*CONDITIONS TO AVOID: THIS MATERIAL IS STABLE FROM A SAFETY POINT OF VIEW.

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

SPILL: WEAR APPROVED RESPIRATOR AND CHEMICALLY COMPATIBLE GLOVES. VACUUM OR SWEEP UP SPILLAGE. AVOID CONTACT. 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/MSHA-APPROVED

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

SPECIAL PRECAUTIONS: STORE IN A 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. 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: E.D./R.H./O.L.
T.K. (10/16/91)

REVISION 3:
R&D:
DATE:

DATE: 5/18/89