

ALCON LABORATORIES -- CIPROFLOXACIN SOLUTION, CILOXAN, 0065-0656-10
MATERIAL SAFETY DATA SHEET
NSN: 650500N043618
Manufacturer's CAGE: 16703
Part No. Indicator: A
Part Number/Trade Name: CIPROFLOXACIN SOLUTION, CILOXAN, 0065-0656-10

General Information

Company's Name: ALCON LABORATORIES INC
Company's Street: 6201 SOUTH FREEWAY
Company's City: FORT WORTH
Company's State: TX
Company's Country: US
Company's Zip Code: 76134
Company's Emerg Ph #: 817-551-4444
Company's Info Ph #: 817-551-4444
Record No. For Safety Entry: 001
Tot Safety Entries This Stk#: 001
Status: SMJ
Date MSDS Prepared: 27JUN91
Safety Data Review Date: 02OCT95
MSDS Serial Number: BSYWL
Hazard Characteristic Code: N1

Ingredients/Identity Information

Proprietary: NO
Ingredient: CIPROFLOXACIN HYDROCHLORIDE MONOHYDRATE. LD50: (ORAL, RAT) <500 MG/KG.
Ingredient Sequence Number: 01
Percent: 0.35
NIOSH (RTECS) Number: 1009905CH
OSHA PEL: N/K (FP N)
ACGIH TLV: N/K (FP N)

Proprietary: NO
Ingredient: ACETIC ACID, SODIUM SALT; (SODIUM ACETATE)
Ingredient Sequence Number: 02
Percent: 0.03
NIOSH (RTECS) Number: AJ4300010
CAS Number: 127-09-3
OSHA PEL: N/K (FP N)
ACGIH TLV: N/K (FP N)

Proprietary: NO
Ingredient: ACETIC ACID (SARA III)
Ingredient Sequence Number: 03
Percent: 0.04
NIOSH (RTECS) Number: AF1225000
CAS Number: 64-19-7
OSHA PEL: 10 PPM
ACGIH TLV: 10 PPM;15 PPM STEL

Proprietary: NO
Ingredient: MANNITOL
Ingredient Sequence Number: 04
Percent: 4.6
NIOSH (RTECS) Number: OP2050000
CAS Number: 87-78-5
OSHA PEL: N/K (FP N)
ACGIH TLV: N/K (FP N)

Proprietary: NO
Ingredient: ACETIC ACID, (ETHYLENEDINITRILIO) TETRA-; (EDTA)
Ingredient Sequence Number: 05
Percent: 0.05
NIOSH (RTECS) Number: AH4025000
CAS Number: 60-00-4
OSHA PEL: N/K (FP N)
ACGIH TLV: N/K (FP N)

Proprietary: NO
Ingredient: BAC
Ingredient Sequence Number: 06
Percent: 0.006
NIOSH (RTECS) Number: 1009981BA
OSHA PEL: N/K (FP N)
ACGIH TLV: N/K (FP N)

Physical/Chemical Characteristics

Appearance And Odor: AQUEOUS SOLUTION.
Boiling Point: N/A
Melting Point: N/A
Vapor Pressure (MM Hg/70 F): N/A
Vapor Density (Air=1): N/A
Specific Gravity: N/A
Evaporation Rate And Ref: NOT APPLICABLE
Solubility In Water: SOLUBLE

Fire and Explosion Hazard Data

Flash Point: NOT APPLICABLE
Lower Explosive Limit: N/A
Upper Explosive Limit: N/A
Extinguishing Media: USE EXTINGUISHING MEDIA APPROPRIATE FOR THE SURROUNDING FIRE CONDITIONS.
Special Fire Fighting Proc: USE NIOSH/MSHA APPROVED SCBA & FULL PROTECTIVE EQUIPMENT (FP N).
Unusual Fire And Expl Hazrds: TOXIC GASES PRODUCED: CARBON DIOXIDE, CARBON MONOXIDE, NITROGEN OXIDES.

Reactivity Data

Stability: YES
Cond To Avoid (Stability): THIS PRODUCT IS STABLE FROM A SAFETY POINT OF VIEW.
Materials To Avoid: NONE OTHER THAN WATER ALONE WOULD PRODUCE.
Hazardous Decomp Products: WHEN HEATED TO DECOMP, MATL EMITS TOXIC FUMES.
TOXIC GASES PRODUCED:CARBON DIOXIDE, CARBON MONOXIDE, NITROGEN OXIDES.
Hazardous Poly Occur: NO
Conditions To Avoid (Poly): NOT RELEVANT

Health Hazard Data

LD50-LC50 Mixture: SEE INGREDIENT 1.
Route Of Entry - Inhalation: YES
Route Of Entry - Skin: NO
Route Of Entry - Ingestion: YES
Health Haz Acute And Chronic: THIS PROD CONFORMS TO FDA REGS & GUIDELINES FOR AN OPHTHALMIC FORMULATION THAT HAS BEEN EXTENSIVELY TESTED & DEMONSTRATED TO BE SAFE FOR USE IN EYE & IT IS NOT EXPECTED TO PRDCE DERMAL IRRIT. EXAGGERATED OCULAR EXPOS IN ANIMALS HAS ELICITED MIN-TO-MOD CONJ IRRIT. IMMATURE DOGS EXPOS BY CIPROFLOXACIN (EFTS OF OVEREXP)
Carcinogenicity - NTP: NO
Carcinogenicity - IARC: NO

Carcinogenicity - OSHA: NO

Explanation Carcinogenicity: NOT RELEVANT

Signs/Symptoms Of Overexp: HLTH HAZ:ORALLY AT DOSAGES OF 30 MG/KG/DAY FOR 4 WKS EXHIBITED MIN TOX IN WT-BEARING JOINTS (ARTHROPATHY). EQUIV HUMAN EXPOS WOULD REQUIRED INGEST OF 600 ML OF CIPROFLOXACIN OPHTHALMIC SOLN (CONTENTS OF 30 5ML DROPTAINERS FOR A 20 KG PERS). RPTD EXPOS TO SOME COMPONENTS OF MIXT MAY LEAD TO DEVEL OF SENSIT.

Med Cond Aggravated By Exp: PERSONS KNOWN TO BE SENSITIZED TO ANY COMPONENT OF THE MIXTURE, OR HAVING SYMPTOMS OF SENSITIZATION TO THE MIXTURE, SHOULD AVOID EXPOSURE.

Emergency/First Aid Proc: INHAL:REMOVE TO FRESH AIR. SUPPORT BRTHG (GIVE O₂/ARTF RESP) (FP N). SKIN/EYE:REMOVE FROM EXPOS & IMMED FLUSH EXPOS AREA W/COPIOUS AMTS OF WATER FOR AT LST 15 MINS. INGEST:INFO ON OVERDOSAGE IN HUMANS IS NOT AVAIL. IN EVENT OF ACUTE OVEREXP, STOM SHOULD BE EMPTIED BY INDUCING VOMIT/BY GASTRIC LAVAGE & PATIENT CAREFULLY OBSERVED & GIVEN SUPPORTIVE TREATMENT. IN EXTREME CASES, DIALYSIS MAY (SUPDAT)

===== Precautions for Safe Handling and Use =====

Steps If Matl Released/Spill: WEAR NIOSH/MSHA APPROVED RESPIRATOR & 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 & WASH SPILL SITE.

Neutralizing Agent: NONE SPECIFIED BY MANUFACTURER.

Waste Disposal Method: DISPOSE I/A/W ALL APPLICABLE FEDERAL, STATE & LOCAL ENVIRONMENTAL REGULATIONS. THIS PRODUCT DOES NOT MEET THE DEFINITION OF HAZARDOUS WASTE AS DEFINED IN 40 CFR, PART 261.11.

Precautions-Handling/Storing: STORE IN TIGHT CNTNR AS DEFINED IN U.S. PHARMACOPEIA. MATL SHOULD BE HNDLD & STORED PER LBL & OTHER INSTRUCTIONS TO ENSURE PRODUCT INTEGRITY.

Other Precautions: AVOID CONT W/EYES, SKIN/CLTHG. AVOID BRTHG DUST/MIST. DO NOT PERMIT EATING, DRINKING/SMOKING NEAR MATL. THIS PROD DOES NOT POSE UNREASONABLE RISK TO HLTH & SAFETY/PROPERTY WHEN TRANSPORTED IN COMMERCE. INFO IN SPECIAL PROT INFO (SUPDAT)

===== Control Measures =====

Respiratory Protection: NIOSH/MSHA APPROVED RESPIRATOR.

Ventilation: USE GENERAL OR LOCAL EXHAUST.

Protective Gloves: RUBBER GLOVES.

Eye Protection: ANSI APPRVD CHEM WORKER GOGGLES (FP N).

Other Protective Equipment: APPROPRIATE LABORATORY APPAREL TO PROTECT EXPOSED SKIN.

Work Hygienic Practices: WASH THOROUGHLY AFTER HANDLING.

Suppl. Safety & Health Data: FIRST AID PROC:BE REQD TO REMOVE DRUG (CIPROFLOXACIN) FROM BODY. OTHER PREC:SECTION ASSUMES LG QTYS OF PROD SUCH AS MIGHT BE ENCOUNTERED IN WAREHOUSE STORAGE OR AN INDUSTRIAL ACCIDENT.

===== Transportation Data =====

===== Disposal Data =====

===== Label Data =====

Label Required: YES

Technical Review Date: 09SEP93

Label Date: 03SEP93

Label Status: G

Common Name: CIPROFLOXACIN SOLUTION, CILOXAN, 0065-0656-10

Chronic Hazard: NO

Signal Word: CAUTION!

Acute Health Hazard-Slight: X

Contact Hazard-Slight: X

Fire Hazard-None: X

Reactivity Hazard-None: X

Special Hazard Precautions: AVOID EYE, SKIN OR CLOTHING CONTACT. AVOID BREATHING DUST OR MIST. ACUTE:SKIN OR EYE CONTACT MAY CAUSE IRRITATION. CHRONIC:NONE LISTED BY MANUFACTURER.

Protect Eye: Y

Protect Skin: Y

Protect Respiratory: Y

Label Name: ALCON LABORATORIES INC

Label Street: 6201 SOUTH FREEWAY

Label City: FORT WORTH

Label State: TX

Label Zip Code: 76134

Label Country: US

Label Emergency Number: 817-551-4444