

MATERIAL SAFETY DATA INFORMATION

DATE: 17-APR-2003

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MANUFACTURER/SOURCE OF INFORMATION: ALCON LABORATORIES, INC.
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FORT WORTH, TX 76134

SECTION 1.	CHEMICAL IDENTIFICATION
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CHEMICAL NAME AND SYNONYMS:
VIGAMOX OPHTHALMIC SOLUTION;
MOXIFLOXACIN HCL 0.5% OPHTHALMIC SOLUTION WITH BORIC ACID AND NACL

SECTION 2.	COMPOSITION/INFORMATION ON INGREDIENTS
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CAS NO.: AP0001533
PMA/NDA: 21-598
PRODUCT CODE: 0065-4013-07 (3ML)

PERCENTAGE:	COMPONENT:
0.545%	MOXIFLOXACIN HCL
	BORIC ACID
	SODIUM CHLORIDE
ADJUST PH	HYDROCHLORIC ACID
ADJUST PH	SODIUM HYDROXIDE
QS TO 100%	PURIFIED WATER

FORMULATION PROPRIETARY: WE WILL MAKE THIS INFORMATION AVAILABLE
TO MEDICAL PERSONNEL IN CASE OF
EMERGENCY.

SECTION 3.	HAZARDS IDENTIFICATION
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TOXIC:
THE ORAL LD50 FOR MOXIFLOXACIN IS 1320 MG/KG AND 1500 MG/KG IN RATS
AND CYNOMOLGUS MONKEYS, RESPECTIVELY. MOXIFLOXACIN IS NOT
TERATOGENIC IN RATS, RABBITS OR CYNOMOLGUS MONKEYS.

TARGET ORGANS:
THREE MONTHS OF TOPICAL OCULAR DOSING WITH UP TO 3% MOXIFLOXACIN
OPHTHALMIC SOLUTION DID NOT ELICIT OCULAR OR SYSTEMIC TOXICITY.

CARCINOGENICITY:

AN ACCELERATED CARCINOGENICITY STUDY OF MOXIFLOXACIN IN RATS AT
ORAL DOSES UP TO 500 MG/KG PER DAY DID NOT PRODUCE
CARCINOGENICITY.

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SECTION 4. FIRST AID MEASURES

INHALATION: REMOVE TO FRESH AIR. SEEK MEDICAL ATTENTION.

SKIN CONTACT: REMOVE CONTAMINATED CLOTHING. WASH EXPOSED AREA WITH SOAP AND WATER. SEEK MEDICAL ADVICE/ATTENTION.

EYE CONTACT: FLUSH EYES WITH WATER. SEEK MEDICAL ADVICE/ATTENTION.

INGESTION: FLUSH MOUTH WITH WATER. SEEK MEDICAL ADVICE/ATTENTION.

SECTION 5. FIRE FIGHTING MEASURES

FLASH POINT: N/A

UPPER EXPLOSION LIMIT: N/A

LOWER EXPLOSION LIMIT: N/A

EXTINGUISHING MEDIA: WATER SPRAY, DRY CHEMICAL, CARBON DIOXIDE, OR FOAM, AS APPROPRIATE FOR SURROUNDING MATERIALS AND FIRE.

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

TOXIC GASES PRODUCED: NOX AND SOX

UNUSUAL FIRE AND EXPLOSION HAZARDS: EMITS TOXIC FUMES

CERCLA HAZARD RATING (SCALE 0-3):

HEALTH: N/A

FIRE: N/A

REACTIVITY: N/A

PERSISTENCE: N/A

SECTION 6. ACCIDENTAL RELEASE MEASURES

SPILL:

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PROPRIETARY

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.

SECTION 7.	HANDLING AND STORAGE
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SPECIAL PRECAUTIONS:

HANDLE ALL PHARMACEUTICAL PRODUCTS IN A WAY THAT WILL AVOID CONTACT WITH AND INHALATION OF DUST FUMES, MISTS, AND/OR VAPORS ASSOCIATED WITH THE PRODUCT. STORE AT ROOM TEMPERATURE.

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.

SECTION 8.	EXPOSURE CONTROLS/PERSONAL PROTECTION
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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

FIRE FIGHTING: 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 GLASSES/GOGGLES

RESPIRATORY PROTECTION: NIOSH/MSHA-APPROVED

SECTION 9.	PHYSICAL AND CHEMICAL PROPERTIES
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APPEARANCE AND ODOR:		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:	ALL
		COMPONENTS ARE WATER SOLUBLE	
VAPOR DENSITY:	N/A		

SECTION 10.	STABILITY AND REACTIVITY
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REACTIVITY: STABLE

INCOMPATIBILITIES: NONE KNOWN

DECOMPOSITION: EMITS TOXIC FUMES INCLUDING NOX AND SOX

POLYMERIZATION: WILL NOT OCCUR

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

SECTION 11.	TOXICOLOGICAL INFORMATION
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TOXICITY:

REPEATED DOSE TOPICAL OCULAR STUDIES IN RABBITS AND MONKEYS WITH UP TO 3% MOXIFLOXACIN OPHTHALMIC SOLUTION DID NOT ELICIT OCULAR OR SYSTEMIC TOXICITY. MOXIFLOXACIN WAS NOT TERATOGENIC IN RATS, RABBITS OR CYNOMOLGUS MONKEYS.

CARCINOGENICITY:

AN ACCELERATED (6 MONTH) CARCINOGENICITY STUDY OF MOXIFLOXACIN IN RATS AT ORAL DOSES UP TO 500 MG/KG PER DAY DID NOT PRODUCE CARCINOGENICITY.

ACUTE EFFECTS--

INHALATION: MAY CAUSE RESPIRATORY TRACT IRRITATION.
FIRST AID: REMOVE TO FRESH AIR. SEEK MEDICAL ATTENTION.

SKIN CONTACT: NO DERMAL IRRITATION IS EXPECTED FROM ACUTE EXPOSURE TO THE SKIN.
FIRST AID: REMOVE CONTAMINATED CLOTHING. WASH EXPOSED AREA WITH SOAP AND WATER. SEEK MEDICAL ADVICE/ATTENTION.

INGESTION: NO UNTOWARD EFFECTS ARE EXPECTED FROM ACUTE ORAL EXPOSURE. THE LD50 IN RATS FOLLOWING ORAL ADMINISTRATION IS 1320 MG/KG.
FIRST AID: FLUSH MOUTH WITH WATER. SEEK MEDICAL ADVICE/ATTENTION.

EYE CONTACT: THIS PRODUCT IS FORMULATED FOR USE IN THE EYE AND IS NOT EXPECTED TO PRODUCE UNTOWARD EFFECTS FOLLOWING ACUTE EXPOSURE.

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FIRST AID: FLUSH EYES WITH WATER. SEEK MEDICAL
ADVICE/ATTENTION.

CHRONIC EFFECTS—

INHALATION: POSSIBLE HYPERSENSITIZATION.

SKIN CONTACT: REPEATED CHRONIC EXPOSURE MAY RESULT IN
HYPERSENSITIVITY IN SUSCEPTIBLE INDIVIDUALS.

INGESTION: POSSIBLE DIARRHEA AND/OR STOMACH DISCOMFORT.

EYE CONTACT: CHRONIC TOPICAL OCULAR STUDIES HAVE NOT BEEN
CONDUCTED WITH MOXIFLOXACIN OPHTHALMIC
SOLUTION, BUT IN A 3-MONTH STUDY OF MOXIFLOXACIN
OPHTHALMIC SOLUTION IN CYNOMOLGUS MONKEYS,
TOPICAL OCULAR ADMINISTRATION OF UP TO 3%
MOXIFLOXACIN OPHTHALMIC SOLUTION DID NOT ELICIT
OCULAR OR SYSTEMIC TOXICITY.

SECTION 12.	ECOLOGICAL INFORMATION
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DATA NOT YET AVAILABLE

SECTION 13.	DISPOSAL INFORMATION
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DISPOSAL: DISPOSE OF IN ACCORDANCE WITH ALL APPLICABLE FEDERAL,
STATE AND LOCAL LAWS. THIS PRODUCT DOES NOT MEET THE
DEFINITION OF A HAZARDOUS WASTE AS DEFINED IN 40CFR,
PART 261.11.

SECTION 14.	TRANSPORTATION INFORMATION
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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.

SECTION 15.	REGULATORY INFORMATION
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CAS NO.: AP0001533 UN NO.: N/A
PRODUCT CODE: 0065-4013-07 (3ML) PMA/NDA NO.: 21-598
TSCA: N/A

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SECTION 16.**OTHER INFORMATION**

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