



## Alcon Labs MSDS System

ALCON LABORATORIES  
1% VEXOL OPHTHALMIC  
SUSPENSION

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NFPA



HMIS

Health	1
Flammability	0
Reactivity	0
PPE	NPU

MATERIAL SAFETY DATA INFORMATION

1-SEP-2000

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## SECTION I

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

CHEMICAL NAME AND SYNONYMS: 1% VEXOL OPHTHALMIC SUSPENSION;

CAS NO.: AP0000519

PMA/NDA NO.: NDA 20-474

PRODUCT CODE: NDC 0065-0626-10 (10 ML)  
0065-0626-20 (2.5 ML)  
0065-0626-06 (5 ML)

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:	COMPONENT:
1.0%	RIMEXOLONE
	MANNITOL
	CARBOPOL 934P
	POLYSORBATE 80
	SODIUM CHLORIDE
0.01%	EDETATE DISODIUM
0.01%	BENZALKONIUM CHLORIDE
	SODIUM HYDROXIDE AND/OR SODIUM HYDROCHLORIDE
	PURIFIED WATER

FORMULATION PROPRIETARY:

WE WILL MAKE THIS INFORMATION AVAILABLE TO MEDICAL PERSONNEL IN CASE OF AN EMERGENCY.

EXPOSURE LIMITS: NOT DETERMINED

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## SECTION III (PHYSICAL DATA)

HAZARD DESCRIPTION: 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: RIMEXOLONE IS WATER INSOLUBLE.

VAPOR DENSITY: N/A

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## 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 TO PREVENT CONTACT WITH SKIN AND EYES.

TOXIC GASES PRODUCED: CARBON DIOXIDE, CARBON MONOXIDE

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## SECTION V (HEALTH EFFECTS AND FIRST AID)

### \*TOXICITY:

LOW ORDER OF TOXICITY HAS BEEN SHOWN FOLLOWING BOTH ACUTE AND SUBCHRONIC EXPOSURES IN VARIOUS ANIMALS. RIMEXOLONE HAS NOT DEMONSTRATED MUTAGENICITY, GENOTOXICITY, REPRODUCTIVE TOXICITY, OR SPECIFIC ORGAN TOXICITY. HIGH OR CHRONIC DOSES OF CORTICO-STERIODS HAVE BEEN ASSOCIATED WITH SUPPRESSION OF ADRENAL GLAND SECRETION, CUSHING'S SYNDROME, WATER RETENTION, ELECTROLYTE IMBALANCE, AND HYPERGLYCEMIA.

### CARCINOGENICITY:

NO LONG TERM STUDIES HAVE BEEN CONDUCTED IN ANIMALS TO EVALUATE THE CARCINOGENIC POTENTIAL OF RIMEXOLONE.

### INHALATION--

#### .ACUTE EXPOSURE:

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

.CHRONIC EXPOSURE: SEE ACUTE EXPOSURE

.FIRST AID:  
REMOVE FROM EXPOSURE. IF NOT BREATHING, GIVE ARTIFICIAL RESPIRATION. OBTAIN APPROPRIATE MEDICAL ATTENTION.

SKIN CONTACT--

.ACUTE EXPOSURE:  
THIS PRODUCT CONFORMS TO FDA REGULATIONS AND GUIDELINES FOR AN OPHTHALMIC FORMULATION AND THUS IS NOT EXPECTED TO PRODUCE DERMAL IRRITATION.

.CHRONIC EXPOSURE: N/A

.FIRST AID:  
SHOULD IRRITATION OCCUR, IMMEDIATELY FLUSH SKIN WITH COPIOUS AMOUNTS OF WATER. IN THE EVENT OF ANY ADVERSE 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 AN INDUSTRIAL ACCIDENT.

.CHRONIC EXPOSURE: N/A

.FIRST AID:  
SHOULD IRRITATION OCCUR, IMMEDIATELY FLUSH EYES WITH COPIOUS AMOUNTS OF WATER. IN THE EVENT OF ANY ADVERSE 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 HAZARD OCCUR.

.CHRONIC EXPOSURE: N/A

.FIRST AID:  
WASH OUT MOUTH WITH WATER. IN THE EVENT OF ANY ADVERSE EFFECTS, OBTAIN APPROPRIATE MEDICAL ATTENTION.

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## SECTION VI (REACTIVITY DATA)

REACTIVITY: STABLE

INCOMPATIBILITIES: NONE KNOWN

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

POLYMERIZATION: WILL NOT OCCUR

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

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## SECTION VII (SPILL OR LEAK PROCEDURES)

### SPILL:

WEAR APPROVED RESPIRATOR AND CHEMICALLY COMPATIBLE GLOVES. VACUUM OR SWEEP SPILLAGE. AVOID MIST. PLACE SPILLAGE IN APPROPRIATE CONTAINER FOR WASTE DISPOSAL. WASH CONTAMINATED CLOTHING BEFORE REUSE. 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.

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## 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/GLASSES

RESPIRATORY PROTECTION: NIOSH/MSHA-APPROVED

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## 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.

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## **SECTION X (TRANSPORTATION AND SHIPPING REQUIREMENTS)**

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.