# **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

078937376

N/A



ALCON LABORATORIES
PILOCARPINE
HYDROCHLORIDE
OPHTHALMIC SOLUTION
1%, 2%, 4%, 6%

File Name: 030667
Internal ID:

Internal ID:

**NFPA** 

Revision Date: 8/14/2009

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Specified

#### Additional Details

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DATE: 8/14/09

MANUFACTURER/SOURCE OF INFORMATION: ALCON LABORATORIES, INC.

Health
Flammability
Reactivity
PPE

Health
Flammability
Physical Hazard
PPE

HMIS III

More...

ADDRESS:

6201 SOUTH FREEWAY FORT WORTH, TX 76134

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CHEMTREC:

DOMESTIC NORTH AMERICA: 800-424-9300

INTERNATIONAL, CALL: 703-527-3887 (COLLECT CALLS ACCEPTED)

THIS IS A FALCON PRODUCT

## SECTION 1. CHEMICAL IDENTIFICATION

PRODUCT NAME: PILOCARPINE HYDROCHLORIDE OPHTHALMIC SOLUTION 1%, 2%, 4%, 6%

PMA/NDA: N/A

PRODUCT CODE:

NDC 16314-203-15

NDC 16314-204-15

NDC 16314-206-15 NDC 16314-208-15

# SECTION 2. COMPOSITION / HAZARDOUS INGREDIENTS

OSHA HAZARDOUS COMPONENTS: PILOCARPINE HYDROCHLORIDE

CHEMICAL NAME:

2(3H)-FURANONE, 3-ETHYLDIHYDRO-4((1-METHLY-IH-IMIDAZOL-5-YL)-METHYL)-MONOHYDROCHLORIDE, (3S-CIS)-

CAS NO.: 54-71-7

PERCENTAGE COMPONENT

1%, 2%, 4%, 6% PILOCARPINE HYDROCHLORIDE

<0.1% BENZALKONIUM CHLORIDE

<1% HYDROXYPROPYL METHYLCELLULOSE

<1% BORIC ACID

<1% SODIUM CITRATE (DIHYDRATE)

>85% PURIFIED WATER

FORMULATION PROPRIETARY:

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

## SECTION 3. HAZARDS IDENTIFICATION

#### EMERGENCY OVERVIEW:

THE ORAL-RAT LD50 FOR PILOCARPINE IS: 200 MG/KG. PILOCARPINE IS CLASSIFIED A "TOXIC" BY OSHA.

THIS CHEMICAL MIXTURE IS CLASSIFIED AS "TOXIC", BASED ON THE REPORTED ORAL LD50 IN RATS OF PILOCARPINE. PILOCARPINE IS THE ONLY PHARMACOLOGICALLY ACTIVE INGREDIENT.

PHYSICAL PROPERTIES: AOUEOUS SOLUTION

#### MEDICAL CLASSIFICATION:

PILOCARPINE IS A PARASYMPATHOMIMETIC (CHOLINERGIC) DRUG APPROVED FOR USE IN TREATMENT OF GLAUCOMA.

#### POTENTIAL ADVERSE EFFECT:

PILOCARPINE OPHTHALMIC SOLUTION IS AVAILABLE AT A CONCENTRATION OF UP TO 80 MG/ML AND A VOLUME OF 15 ML, RESULTING IN A UNIT DOSE POTENTIAL OF 1200 MG. EXPOSURE TO THIS AMOUNT MAY RESULT IN PHARMACOLOGIC EFFECTS, BUT IS NOT EXPECTED TO CAUSE SIGNIFICANT TOXICITY. TREATMENT IS SYMPTOMATIC.

## SECTION 4. FIRST AID MEASURES

#### INHALATION:

REMOVE TO FRESH AIR. IF NOT BREATHING, PERFORM ARTIFICIAL RESPIRATION. IF BREATHING IS DIFFICULT, GIVE OXYGEN. OBTAIN APPROPRIATE MEDICAL ATTENTION.

#### SKIN CONTACT:

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

# EYE CONTACT:

IF IRRITATION OCCURS, 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 INGESTION OCCUR. IN THE EVENT OF ANY ADVERSE EFFECTS, OBTAIN APPROPRIATE MEDICAL ATTENTION.

#### SECTION 5. FIRE FIGHTING MEASURES

### EXTINGUISHING MEDIA:

USE EXTINGUISHING MEDIA APPROPRIATE FOR THE SURROUNDING FIRE CONDITIONS

SPECIAL FIRE FIGHTING PROCEDURES:

WEAR SELF-CONTAINED BREATHING APPARATUS AND PROTECTIVE CLOTHING

UNUSUAL FIRE AND EXPLOSION HAZARD:

THIS MATERIAL SHOULD NOT PRESENT A FIRE OR HAZARD.

## SECTION 6. ACCIDENTAL RELEASE MEASURES

WEAR CHEMICALLY COMPATIBLE GLOVES. WIPE UP SPILLED LIQUID WITH ABSORBANT MATERIAL. VACUUM OR SWEEP UP LARGE SPILLS. PLACE SPILLAGE IN APPROPRIATE CONTAINER FOR WASTE DISPOSAL. WASH SPILL SITE. WASH CONTAMINATED CLOTHING BEFORE REUSE.

### SECTION 7. HANDLING AND STORAGE

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

NONE NECESSARY FOR NORMAL PRODUCT HANDLING.

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

CLOTHING: APPROPRIATE APPAREL TO PROTECT EXPOSED SKIN.

GLOVES: RUBBER

EYE PROTECTION: SAFETY GLASSES/GOGGLES

RESPIRATORY PROTECTION: NIOSH/MSHA-APPROVED

# SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AND ODOR: LIQUID

BOILING POINT: COMPARABLE TO WATER

MELTING POINT: N/A

SPECIFIC GRAVITY: COMPARABLE TO WATER

VAPOR PRESSURE: N/A

EVAPORATION RATE: COMPARABLE TO WATER

SOLUBILITY IN WATER: 100%

VAPOR DENSITY: COMPARABLE TO WATER

pH: 6.5 TO 7.5

## SECTION 10. STABILITY AND REACTIVITY

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

#### TOXICITY:

THE ORAL-RAT LD50 FOR PILOCARPINE IS: 200 MG/KG. PILOCARPINE IS CLASSIFIED A "TOXIC" BY OSHA.

THIS CHEMICAL MIXTURE IS CLASSIFIED AS "TOXIC", BASED ON THE REPORTED ORAL LD50 IN RATS. PILOCARPINE IS THE ONLY PHARMACOLOGICALLY ACTIVE INGREDIENT.

#### CARCINOGENICITY:

NO COMPONENTS OF THIS CHEMICAL MIXTURE ARE CLASSIFIED AS CARCINGENIC BY OSHA, THE NTP OR THE IARC.

#### ACUTE EFFECTS:

INHALATION: PILOCARPINE OPHTHALMIC SOLUTION IS NOT AN INHALATION HAZARD

#### SKIN CONTACT:

MINIMAL TO MILD SKIN IRRITATION MAY OCCUR UPON EXPOSURE TO PILOCARPINE OPHTHALMIC SOLUTION.

#### INGESTION:

OVERDOSE MAY CAUSE MIOSIS, EYE REDNESS, SWEATING, SALIVATION, DIARRHEA, GI CRAMPING, VOMITING, HYPOTENSION, CARDIAC ARRHYTHMIAS.

EYE CONTACT: MAY CAUSE TRANSIENT IRRITATION, CONJUNCTIVAL REDNESS, MIOSIS

#### CHRONIC EFFECTS:

INHALATION: PILOCARPINE OPHTHALMIC SOLUTION IS NOT AN INHALATION HAZARD

#### SKIN CONTACT:

MINIMAL TO MILD SKIN IRRITATION MAY OCCUR UPON EXPOSURE TO PILOCARPINE OPHTHALMIC SOLUTION. REPEATED EXPOSURE TO BENZALKONIUM CHLORDIE MAY RESULT IN SKIN SENSITIZATION IN SENSITIVE INDIVIDUALS

#### INGESTION:

EXCESS EXPOSURE OR OVERDOSE MAY CAUSE MIOSIS, EYE REDNESS, SWEATING, SALIVATION, DIARRHEA, GI CRAMPING, VOMITING, HYPOTENSION, CARDIAC ARRHYTHMIAS

# EYE CONTACT:

MAY CAUSE TRANSIENT IRRITATION, CONJUNCTIVAL REDNESS, MIOSIS REPEATED EXPOSURE TO BENZALKONIUM CHLORIDE MAY RESULT IN SENSITIZATION IN SENSITIVE INDIVIDUALS

### SECTION 12. ECOLOGICAL INFORMATION

DATA NOT YET AVAILABLE

## SECTION 13. DISPOSAL INFORMATION

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 14. TRANSPORTATION INFORMATION

THE FOLLOWING LABEL AND SHIPPING INFORMATION IS REQUIRED BY THE U.S. DEPARTMENT OF TRANSPORTATION:

D.O.T. HAZARD DESCRIPTION: CONSUMER COMMODITY

D.O.T. HAZARD CLASS: ORM-D

D.O.T. LABEL REQUIRED: NONE

D.O.T. UN NO: NONE

PACKAGING:

D.O.T. EXCEPTIONS: 173.156,306

D.O.T. NON BULK: 173.156,306

D.O.T. BULK: NONE

MAXIMUM NET QUANTITY IN ONE PACKAGE: PASSENGER CARRYING AIRCRAFT: 30 KG GROSS (D.O.T.) CARGO AIRCRAFT: 30 KG GROSS (D.O.T.)

IATA DESCRIPTION: CONSUMER COMMODITY

IATA UN NO: 8000

IATA HAZARD CLASS: 9

IATA LABEL REQUIRED: MISCELLANEOUS

IATA PKG INSTRUCTIONS: 910

MAXIMUM NET QUANTITY IN ONE PACKAGE: PASSENGER CARRYING AIRCRAFT: 30 KG GROSS (IATA)

CARGO AIRCRAFT: 30 KG GROSS (IATA)

ERG CODE: 9L IATA

## SECTION 15. REGULATORY INFORMATION

TSCA: N/A

PRODUCT CODE: NDC 16314-203-15 NDC 16314-204-15 NDC 16314-206-15 NDC 16314-208-15

# **SECTION 16. OTHER INFORMATION**

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: J.G./F.F.

REVISION: 1

R&D: \*

DATE: 8/14/09

Hosted as Alcon R&D

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# **BSS**

# **ALCON LABORATORIES**

Revised: 6/8/2010

Filename: 044660

This product is also known as  $N\!/\!A$ 

Other Information

Ingredients NO DATA AVAILABLE

**MSDS** 

**Material Safety Data Sheet** 

#### MATERIAL SAFETY DATA INFORMATION

DATE: 6/8/2010

MANUFACTURER/SOURCE OF INFORMATION: ALCON LABORATORIES, INC.

ADDRESS:

6201 SOUTH FREEWAY FORT WORTH, TX 76134

EMERGENCY PHONE: 1-817-551-4444

#### SECTION 1. CHEMICAL IDENTIFICATION

PRODUCT NAME: BSS

PRODUCT CODE:

NDC: 0065-0795-25, 0065-0795-50

#### SECTION 2. HAZARDS IDENTIFICATION

THIS PRODUCT IS NON-HAZARDOUS AND IS APPROVED BY THE FDA. IT IS AN AQUEOUS SOLUTION AND IS NOT CONSIDERED TO CONSTITUTE A HAZARD.

#### OSHA:

A HAZARD DETERMINATION FOR THIS PRODUCT WAS PERFORMED AS SPECIFIED AT 29 CFR, PART 1910.1200, WHICH CONCLUDED THAT THIS PRODUCT DOES NOT MEET THE DEFINITION OF HAZARDOUS, AND THEREFORE DOES NOT REQUIRE A MATERIAL SAFETY DATA SHEET (MSDS). ANY SAFETY CONCERNS REGARDING THIS PRODUCT ARE DESCRIBED ON THE PACKAGE INSERT.

#### DOT:

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

#### EPA:

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  $40\,$  CFR, PART 261.11.

## SECTION 3. OTHER INFORMATION

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 BY: F.F