ATROPINE SULFATE OPHTHALMIC SOLUTION, 1%

ALCON LABORATORIES

Revised: 5/1/2011

MATERIAL SAFETY DATA INFORMATION

DATE: 5/1/2011

MANUFACTURER/SOURCE OF INFORMATION: ALCON LABORATORIES, INC.

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THIS IS A FALCON PHARMACEUTICALS, LTD. PRODUCT

SECTION 1. CHEMICAL IDENTIFICATION

PRODUCT NAME: ATROPINE SULFATE OPHTHALMIC SOLUTION, 1%

PMA/NDA: N/A

PRODUCT CODE:
NDC 61314-303-01 (1%-5 ML)
61314-303-02 (1%-15 ML)

SECTION 2. COMPOSITION / HAZARDOUS INGREDIENTS

OSHA HAZARDOUS COMPONENT: ATROPINE SULFATE

PERCENTAGE	COMPONENT
1%	ATROPINE SULFATE
0.01%	BENZALKONIUM CHLORIDE

<2%	INACTIVE INGREDIENTS
>95%	PURIFIED WATER

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

SECTION 3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:
THIS CHEMICAL MIXTURE IS CLASSIFIED AS "TOXIC", BASED ON THE LOWEST REPORTED ORAL LD50 IN RATS OF 500 MG ATROPINE SULFATE/KG BODY WEIGHT. ATROPINE SULFATE IS THE ONLY PHARMACOLOGICALLY ACTIVE INGREDIENT PRESENT.

PHYSICAL PROPERTIES: AQUEOUS SOLUTION

MEDICAL CLASSIFICATION:
ATROPINE SULFATE IS AN ANTICHOLINERGIC OPHTHALMIC DRUG SOLUTION USED FOR PUPIL DILATION.

POTENTIAL ADVERSE EFFECT:
ATROPINE SULFATE OPHTHALMIC SOLUTION IS AVAILABLE AT A CONCENTRATION OF UP TO 10 MG/ML AND A VOLUME OF 15 ML, RESULTING IN A UNIT DOSE POTENTIAL OF 150 MG. EXPOSURE TO THIS AMOUNT IS NOT EXPECTED TO CAUSE SIGNIFICANT TOXICITY, BUT MAY RESULT IN PHARMACOLOGIC EFFECTS SUCH AS MYDRIASIS, DRY MOUTH, HYPERPNIA, TACHYCARDIA OR RESTLESSNESS. 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 CONTAINER 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 APPRATUS 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 APPARTUS

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

SPECIFIC GRAVITY: COMPARABLE TO WATER

EVAPORATION RATE: COMPARABLE TO WATER

VAPOR DENSITY: COMPARABLE TO WATER

MELTING POINT: N/A

VAPOR PRESSURE: N/A

SOLUBILITY IN WATER: 100%

pH: NEUTRAL

SECTION 10. STABILITY AND REACTIVITY

REACTIVITY: STABLE

INCOMPATIBILITIES: NONE KNOWN

DECOMPOSITION: MAY EMIT 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:
THIS CHEMICAL MIXTURE IS CLASSIFIED AS "TOXIC", BASED ON THE LOWEST REPORTED ORAL LD50 IN RATS OF 500 MG ATROPINE SULFATE/KG BODY WEIGHT. ATROPINE SULFATE IS THE ONLY PHARMACOLOGICALLY ACTIVE INGREDIENT PRESENT.

THE ORAL RAT LD50 FOR ATROPINE SULFATE IS: 500 - 622 MG/KG.

THE PRODUCT CONTAINS UP TO 10 MG ATROPINE SULFATE PER ML SOLUTION, AND A VOLUME OF 15 ML. THUS, A MAXIMUM OF 150 MG IS AVAILABLE PER CONTAINER, AND RISK OF TOXICITY IS LOW, BUT MAY RESULT IN PHARMACOLOGIC EFFECTS SUCH AS MYDRIASIS, DRY MOUTH, HYPERPNIA, TACHYCARDIA OR RESTLESSNESS. TREATMENT IS SYMPTOMATIC.

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

ACUTE EFFECTS:

INHALATION:
ATROPINE SULFATE OPHTHALMIC SOLUTION IS NOT AN INHALATION HAZARD

SKIN CONTACT:
MINIMAL TO MILD SKIN IRRITATION MAY OCCUR UPON EXPOSURE TO ATROPINE SULFATE OPHTHALMIC SOLUTION. REPEATED EXPOSURE TO BENZALKONIUM CHLORIDE MAY RESULT IN SKIN SENSITIZATION IN SENSITIVE INDIVIDUALS.

INGESTION:
ORAL INGESTION MAY CAUSE DRY MOUTH, DYSPHAGIA, CONSTIPATION MYDRIASIS, RESTLESSNESS, DELIRIUM, ATAXIA, TREMBLING, CONVULSION, TACHYCARDIA AND HYPERPNIA.

EYE CONTACT:
MAY CAUSE TRANSIENT IRRITATION, CONJUNCTIVAL BLANCHING, MYDRIASIS.

CHRONIC EFFECTS:

INHALATION:
ATROPINE SULFATE OPHTHALMIC SOLUTION IS NOT AN INHALATION HAZARD

SKIN CONTACT:

MINIMAL TO MILD SKIN IRRITATION MAY OCCUR UPON EXPOSURE TO ATROPINE SULFATE OPHTHALMIC SOLUTION. REPEATED EXPOSURE TO BENZALKONIUM CHLORIDE MAY RESULT IN SKIN SENSITIZATION IN SENSITIVE INDIVIDUALS

INGESTION:
ORAL INGESTION MAY CAUSE DRY MOUTH, DYSPHAGIA, CONSTIPATION, MYDRIASIS, RESTLESSNESS, DELIRIUM, ATAXIA, TREMBLING, CONVULSION, TACHYCARDIA AND HYPERPNIA,

EYE CON TACT:
MAY CAUSE TRANSIENT IRRITATION, CONJUNCTIVAL BLANCHING, MYDRIASIS

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 40 CFR, PART 261.11.

SECTION 14. TRANSPORTATION INFORMATION

THIS COMPOUND SHOULD 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.

SECTION 15. REGULATORY INFORMATION

TSCA: N/A

UN NO.: N/A

PMA/NDA NO.: N/A

PRODUCT CODE:
NDC 61314-303-01 (1%-5 ML)
61314-303-02 (1%-15 ML)

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: F.F.

REVISION: 1

R&D: *