
AMOTOSALEN SOLUTION IN PL2411 PLASTIC CONTAINER

BAXTER HEALTHCARE

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Other Information

Product Code: FX1021
GURX0059
GURX0060
GURX68B
GURX69B
R5628B
R5629B

MSDS

Material Safety Data Sheet

BAXTER

MATERIAL SAFETY DATA SHEET:
AMOTOSALEN SOLUTION IN PL2411 PLASTIC CONTAINER

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SECTION 1: IDENTIFICATION

TRADE/COMMON NAMES: AMOTOSALEN SOLUTION IN PL2411 PLASTIC CONTAINERS

PRODUCT CODE(S): FX1021, GURX0059, GURX0060, GURX68B, GURX69B, R5629B, R5628B.

DESCRIPTION:

ISOTONIC SALINE SOLUTION CONTAINING 1 MG/ML AMOTOSALEN (PSORALEN DERIVATIVE).

PRODUCT USE: FOR ADDITION TO BLOOD COMPONENTS PRIOR TO TRANSFUSION

SECTION 2: COMPOSITION AND INFORMATION ON INGREDIENTS

COMPONENT	CAS NUMBER	%	EXPOSURE LIMITS	NOTES
3-[(2-AMINOETHOXY)METHYL]-2,5,9-TRIMETHYL-7H-FURO[3,2-G][1]BENZOPYRAN-7-ONE-HYDROCHLORIDE (AMOTOSALEN)	161262-45-9	<1	a,b*	NONE
SODIUM CHLORIDE	7647-14-5	<1	a,b*	NONE
WATER	7732-18-5	>98	NE	NONE

KEY:

NE = NOT ESTABLISHED

- (a) PARTICULATES NOT OTHERWISE CLASSIFIED (PNO), TWA INHALABLE PARTICULATE: 10 MG/M3, RESPIRABLE PARTICULATE: 3 MG/M3
- (b) PARTICULATES NOT OTHERWISE REGULATED (PNOR), TWA TOTAL DUST: 15 MG/M3, RESPIRABLE FRACTION: 5 MG/M3

KEY TO NOTES:

- (1) (SUSPECT) CARCINOGEN - OSHA, ACGIH, NTP OR IARC
- (2) SARA TITLE III SECTION 313 CHEMICAL
- (3) SARA TITLE III EXTREMELY HAZARDOUS SUBSTANCE
- (4) CERCLA HAZARDOUS SUBSTANCE AND REPORTABLE QUANTITIES
- (5) RCRA HAZARDOUS WASTE

NONE - NONE OF THE ABOVE APPLIES TO THIS COMPONENT

* FINAL PRODUCT IS A SOLUTION. THE HAZARDS OF THE COMPONENTS ARE NOT ANTICIPATED. PARTICULATE EXPOSURE HAZARD MAY BE PRODUCED BY AEROSOLIZATION.

SECTION 3: HAZARD IDENTIFICATION

EMERGENCY OVERVIEW:

NONVOLATILE, NONFLAMMABLE MIXTURE IN SALT WATER PACKAGED IN QUANTITIES OF 15-17.5 ML (APPROXIMATELY 1/2 TO 1 OUNCE) IN PLASTIC CONTAINERS. PLASTIC CONTAINER, CONTAINING AMOTOSALEN SOLUTION, SHOULD NOT RESULT IN EXPOSURE OR PRESENT A HAZARD.

IF CONTAINERS ARE FOUND BROKEN OR DAMAGED, AVOID AMOTOSALEN SOLUTION CONTACT WITH SKIN AND EYES.

EXPOSURE TO SUNLIGHT AFTER EYE OR SKIN CONTACT MAY CAUSE A SUNBURN-LIKE REACTION.

KEEP AWAY FROM SUNLIGHT AFTER DIRECT CONTACT.

AFTER CONTACT WITH SKIN, WASH IMMEDIATELY WITH PLENTY OF WATER.

THE FOLLOWING WARNING IS FOR AMOTOSALEN SOLUTION:

MUTAGENIC IN CELL CULTURE (IN VITRO) GENETIC TOXICOLOGY TEST SYSTEMS.

THE HAZARDS LISTED ARE FOR EXPOSURE TO THE AMOTOSALEN SOLUTION

EYES:

MAY BE SLIGHTLY IRRITATING AND MAY CAUSE DISCHARGE FROM THE EYE, IF EXPOSURE TO SUNLIGHT OCCURS AFTER EYE CONTACT.

SKIN:

ONE-TIME OR REPEATED EXCESSIVE SKIN CONTACT, FOLLOWED BY EXPOSURE TO SUNLIGHT AFTER CONTACT CAN CAUSE A SUNBURN-LIKE REACTION. MAY CAUSE EYE IRRITATION AND DISCHARGE AFTER SKIN CONTACT AND EXPOSURE TO SUNLIGHT (BASED UPON ACTIVE INGREDIENT, AMOTOSALEN). ONE-TIME CONTACT WITH THE FORMULATION IS EXPECTED TO BE NON-TOXIC (SHORT TERM). REPEATED SKIN CONTACT MAY CAUSE SKIN SENSITIZATION.

INHALATION:

NO DATA AVAILABLE. IF SYSTEMIC OVEREXPOSURE OCCURS, FOLLOWED BY EXPOSURE TO SUNLIGHT, MAY CAUSE A SUNBURN-LIKE REACTION AND IRRITATION AND DISCHARGE FROM THE EYE.

INGESTION:

FORMULATION IS NOT EXPECTED TO BE TOXIC IF THE CONTENT OF ONE CONTAINER IS ACCIDENTALLY SWALLOWED.

SECTION 4: FIRST AID MEASURES

EYES:

FLUSH WITH LARGE AMOUNT OF WATER FOR AT LEAST 15 MINUTES. KEEP AWAY FROM SUNLIGHT. SEEK MEDICAL ATTENTION IF IRRITATION OCCURS.

SKIN:

REMOVE CONTAMINATED CLOTHING, WASH THE AFFECTED AREA WITH MILD DETERGENT AND WATER. FLUSH AREA WITH WATER FOR AT LEAST 15 MINUTES. KEEP AWAY FROM SUNLIGHT. IF REDNESS OR IRRITATION OCCURS, SEEK MEDICAL ATTENTION.

INHALATION:

REMOVE PERSON TO FRESH AIR. KEEP AWAY FROM SUNLIGHT. IF PERSON IS NOT BREATHING, ADMINISTER ARTIFICIAL RESPIRATION OR CPR. IF BREATHING IS DIFFICULT, GIVE OXYGEN. SEEK MEDICAL ATTENTION, IF APPROPRIATE.

INGESTION:

CALL A PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. DO NOT INDUCE VOMITING UNLESS DIRECTED TO DO SO BY MEDICAL PERSONNEL. NEVER GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON. GET MEDICAL ATTENTION IF SYMPTOMS APPEAR. KEEP AWAY FROM SUNLIGHT.

SECTION 5: FIRE-FIGHTING MEASURES

EXTINGUISHING MEDIA:

USE MEDIUM (E.G., WATER, FOAM, VAPORIZING LIQUID OR MULTIPURPOSE DRY CHEMICAL) SUITABLE FOR SURROUNDING MATERIALS.

FIRE-FIGHTING PROCEDURES:

FIRE FIGHTER SHOULD WEAR FULL-FACE POSITIVE PRESSURE SELF-CONTAINED BREATHING APPARATUS (SCBA), GLOVES AND FULL SKIN PROTECTION.

UNUSUAL FIRE/EXPLOSION HAZARDS: NONE KNOWN

HAZARDOUS DECOMPOSITION PRODUCTS: DATA NOT AVAILABLE

FLASH POINT: NOT DETERMINED
NOT DETERMINED

METHOD: NOT APPLICABLE
METHOD: NOT APPLICABLE

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:

IF POTENTIAL EXISTS FOR AEROSOLIZATION OF PRODUCT, IMMEDIATELY CONTACT EMERGENCY PERSONNEL AND KEEP UNNECESSARY PERSONNEL AWAY. USE SUITABLE PROTECTIVE EQUIPMENT (SECTION 8). FOLLOW ALL FIRE-FIGHTING PROCEDURES.

ENVIRONMENTAL PRECAUTIONS AND CLEAN-UP METHODS:

FOR SMALL SPILLS, WEAR PROTECTIVE CLOTHING (SECTION 8) AND TAKE PROPER PRECAUTIONS TO MINIMIZE EXPOSURE. SOAK UP LIQUID WITH ABSORBENT MATERIAL AND PLACE IN A SEALED, LIQUID PROOF CONTAINER FOR DISPOSAL. WASH SPILL AREA WITH SOAP AND WATER.

SECTION 7: HANDLING AND STORAGE

HANDLING: PROTECT FROM LIGHT.

STORAGE: ROOM TEMPERATURE (25 DEG. C/77 DEG. F) OR LOWER

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

OCCUPATIONAL EXPOSURE LIMITS:

REFER TO SECTION 2 FOR COMPONENT EXPOSURE LIMITS. NO OCCUPATIONAL EXPOSURE LIMITS HAVE BEEN ESTABLISHED BY OSHA, ACGIH OR NIOSH FOR THE FORMULATION.

ENGINEERING CONTROLS:

NONE REQUIRED AS THE MATERIAL IS CONTAINED IN A PLASTIC POUCH. IF POTENTIAL EXISTS FOR EXPOSURE TO MIST OR AEROSOLIZATION, HANDLE THE MATERIAL IN AN ENCLOSED OR VENTILATED AREA, SUCH AS A VENTILATED ENCLOSURE OR HOOD.

PERSONAL PROTECTIVE EQUIPMENT:

RESPIRATORY PROTECTION:

PERFORM EXPOSURE MONITORING FOR THIS PRODUCT AND ITS COMPONENTS TO ENSURE THAT EMPLOYEES ARE NOT EXPOSED TO LEVELS GREATER THAN APPLICABLE REGULATORY LIMITS. IF EXPOSURE LEVELS EXCEED REGULATORY LIMITS, IMPLEMENT A RESPIRATORY PROTECTION

PROGRAM INCLUDING RESPIRATORY PROTECTION THAT IS IN COMPLIANCE WITH OSHA 29 CFR 1910.134 (IN THE US) OR EQUIVALENT REGULATION IN OTHER REGIONS. FIRE FIGHTING REQUIRES THE USE OF A SELF-CONTAINED BREATHING APPARATUS WITH FULL FACE PIECE AND POSITIVE PRESSURE MODE.

SKIN:

NONE REQUIRED AS THE MATERIAL IS CONTAINED IN A PLASTIC POUCH. IF POTENTIAL FOR EXPOSURE EXISTS, WEAR DISPOSABLE, WATER RESISTANT, LAB COAT OR EQUIVALENT (E.G., TYVEK TYPE COVERALLS) AND DISCARD APPROPRIATELY. THE CHOICE OF SKIN PROTECTION SHOULD BE APPROPRIATE FOR THE JOB ACTIVITY BEING CONDUCTED AND THE EXPOSURE POTENTIAL.

HANDS:

NONE REQUIRED AS THE MATERIAL IS CONTAINED IN A PLASTIC POUCH. IF POTENTIAL FOR EXPOSURE EXISTS, LATEX OR OTHER IMPERVIOUS GLOVES SHOULD BE WORN.

EYES:

NONE REQUIRED AS THE MATERIAL IS CONTAINED IN A PLASTIC POUCH. IF POTENTIAL FOR EXPOSURE EXISTS, USE SAFETY GLASSES WITH SIDE SHIELDS OR GOGGLES, FACE SHIELD, OR OTHER FULL-FACE PROTECTION IF POTENTIAL EXISTS FOR DIRECT EXPOSURE TO AEROSOLS OR SPLASHES.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: CLEAR, COLORLESS, LIQUID

PH: 4.0 - 6.0

BOILING POINT: NOT DETERMINED

VAPOR DENSITY (AIR = 1): NOT DETERMINED

VAPOR PRESSURE: NOT DETERMINED

SOLUBILITY IN WATER: MISCIBLE

EVAPORATION RATE (DIETHYL ETHER = 1): NOT APPLICABLE

SECTION 10: STABILITY AND REACTIVITY

STABLE: STABLE UNDER NORMAL STORAGE AND HANDLING CONDITIONS (SECTION 7)

INCOMPATIBILITY (MATERIALS TO AVOID): UV LIGHT EXPOSURE

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY

AMOTOSALEN:

LD50 ORAL, RAT, MALE: 981 MG/KG

LD50 ORAL, RAT, FEMALE: 799 MG/KG

LD50 DERMAL, RABBIT: >2000 MG/KG

PRIMARY EYE IRRITATION: MODERATE IRRITANT

DERMAL PHOTOIRRITATION: MODERATE PHOTOIRRITANT, OCULAR LESIONS IF EYES PHOTOTREATED

AMOTOSALEN (1 MG/ML IN SALINE):

PRIMARY EYE IRRITATION: NON IRRITANT

PRIMARY SKIN IRRITATION: NON IRRITANT

DERMAL PHOTOIRRITATION: SLIGHT PHOTOIRRITANT

DERMAL SENSITIZATION: NON SENSITIZER
DERMAL PHOTOSENSITIZATION: SLIGHT PHOTOSENSITIZER

ACUTE EFFECTS:

EYES:

DIRECT CONTACT IS EXPECTED TO BE NON-IRRITATING BASED ON PRIMARY EYE IRRITATION STUDIES. IF EYE CONTACT OCCURS FOLLOWED BY EXPOSURE TO SUNLIGHT, MAY CAUSE IRRITATION AND DISCHARGE FROM THE EYE.

SKIN:

ONE-TIME EXCESSIVE SKIN CONTACT OF THE FORMULATED MIXTURE FOLLOWED BY EXPOSURE TO SUNLIGHT AFTER CONTACT CAN CAUSE A SUNBURN-LIKE REACTION. THE ACTIVE INGREDIENT, AMOTOSALEN, CAN CAUSE EYE IRRITATION AND DISCHARGE AFTER SKIN CONTACT AND EXPOSURE TO SUNLIGHT. THE ACTIVE INGREDIENT, AMOTOSALEN, WAS NOT TOXIC TO RATS FROM A SINGLE DERMAL DOSE OF 2 G/KG. IN THE FORMULATION MIXTURE, ONE-TIME CONTACT WITH THE FORMULATION IS EXPECTED TO BE NON-TOXIC (SHORT TERM).

INGESTION:

BASED UPON THE LOW CONCENTRATION OF THE ACTIVE INGREDIENT, THE FORMULATED MIXTURE IS NOT EXPECTED TO BE TOXIC IF THE CONTENT OF ONE CONTAINER IS ACCIDENTALLY SWALLOWED.

INHALATION:

NO DATA AVAILABLE. IF SYSTEMIC OVEREXPOSURE OCCURS BY INHALATION, FOLLOWED BY EXPOSURE TO SUNLIGHT, MAY CAUSE A SUNBURN-LIKE REACTION.

CHRONIC EFFECTS:

FOR COMPARISON PURPOSES WITH THE DOSAGES LISTED IN THE FOLLOWING SECTIONS: IF THE ENTIRE CONTENTS OF 1 CONTAINER WERE ACCIDENTALLY SWALLOWED, THE MAXIMUM POSSIBLE EXPOSURE TO AMOTOSALEN WOULD BE 290 (MICRO)G/KG FOR A 60 KG PERSON.

ADVERSE EFFECTS:

BASED ON DERMAL STUDIES IN LABORATORY ANIMALS, REPEATED OVEREXPOSURE OR SKIN CONTACT, FOLLOWED BY EXPOSURE TO SUNLIGHT MAY CAUSE A SUNBURN-LIKE REACTION ON THE SKIN (TARGET ORGAN). REPEATED INTRAVENOUS ADMINISTRATION IN LABORATORY ANIMALS DID NOT CAUSE AMOTOSALEN RELATED TOXICOLOGICAL FINDINGS AT DOSES OF 347 (MICRO)G/KG/DAY IN RATS AND 240 (MICRO)G/KG/DAY IN DOGS IN 13-WEEK STUDIES.

CARCINOGENIC EFFECTS:

IN A TRANSGENIC MOUSE MODEL FOR CARCINOGENICITY, AMOTOSALEN WAS NOT CARCINOGENIC AT DOSES UP TO 977 (MICRO)G.KG/DAY IN MICE DOSED INTRAVENOUSLY 3 TIMES WEEKLY FOR 26 WEEKS. SIMILAR COMPOUNDS TO AMOTOSALEN HAVE PRODUCED SKIN TUMORS WHEN REPEATEDLY ADMINISTERED ORALLY TO LABORATORY ANIMALS FOLLOWED BY ULTRAVIOLET LIGHT EXPOSURE AFTER EACH ADMINISTRATION.

MUTAGENIC EFFECTS:

THE ACTIVE INGREDIENT, AMOTOSALEN, CAUSED MUTATIONS IN SEVERAL IN VITRO (CELL CULTURE) GENETIC TOXICOLOGY TEST SYSTEMS: THE AMES SALMONELLA GENE MUTATION ASSAY, THE MOUSE LYMPHOMA GENE MUTATION ASSAY AND A CHROMOSOMAL ABERRATION STUDY. IT WAS NOT MUTAGENIC IN AN IN VIVO (WHOLE ANIMAL) ASSAY THAT EVALUATED EFFECTS ON DNA OR IN A MOUSE MICRONUCLEUS ASSAY, WHICH EVALUATED CHROMOSOMAL EFFECTS.

DEVELOPMENTAL AND TERATOGENIC EFFECTS:

AMOTOSALEN WAS NOT TERATOGENIC IN STUDIES IN RATS AT INTRAVENOUS DOSES UP TO 351 (MICRO)G/KG/DAY AND IN RABBITS DOSED INTRAVENOUSLY AT 10 (MICRO)G/KG/DAY. AMOTOSALEN DID NOT AFFECT FETAL DEVELOPMENT IN RATS AT INTRAVENOUS DOSES UP TO 460 (MICRO)G/KG/DAY.

REPRODUCTIVE EFFECTS:

AMOTOSALEN WAS NOT A REPRODUCTIVE TOXICANT (AFFECT FERTILITY OR OTHER REPRODUCTIVE PARAMETERS) IN MALE AND FEMALE RATS AT INTRAVENOUS DOSES UP TO 451 (MICRO)G/KG/DAY IN MALES AND 358 (MICRO)G/KG/DAY IN FEMALES.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY DATA: NO DATA AVAILABLE

ENVIRONMENTAL HAZARDS: NOT KNOWN

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD:

DISPOSE OF IN ACCORDANCE WITH COUNTRY, REGIONAL, FEDERAL, STATE, AND LOCAL REGULATIONS. CONSIDERATION TO DISPOSE OF LIQUID WASTES AS PHARMACEUTICAL WASTES SHOULD BE GIVEN.

SECTION 14: TRANSPORTATION INFORMATION

DOT DESIGNATION: NOT REGULATED

IATA DESIGNATION: NOT REGULATED

SECTION 15: REGULATORY INFORMATION

US REGULATIONS:

OSHA PROCESS SAFETY: NOT APPLICABLE

SARA HAZARD CATEGORIES, TITLE III:

ACUTE HAZARD: NO
CHRONIC HAZARD: NO
FIRE HAZARD: NO
REACTIVITY HAZARD: NO
SUDDEN RELEASE HAZARD: NO

TSCA STATUS: EXEMPT: PHARMACEUTICAL MATERIAL - NOT IN INVENTORY

CALIFORNIA PROPOSITION 65: NOT LISTED

REFER TO SECTION 2 FOR ADDITIONAL US REGULATORY STATUS

EUROPEAN UNION RISK AND SAFETY PHRASES:

Xn, R40 POSSIBLE RISK OF IRREVERSIBLE EFFECTS.
S14 KEEP AWAY FROM SUNLIGHT.
S24 AVOID CONTACT WITH SKIN.
S25 AVOID CONTACT WITH EYES.
S29 AFTER CONTACT WITH SKIN, WASH IMMEDIATELY WITH PLENTY OF WATER

CANADIAN REGULATIONS:

WHMIS: NOT CONTROLLED UNDER WHMIS

SECTION 16: OTHER INFORMATION

MODIFICATIONS:

ADDITIONAL INFORMATION HAS BEEN ADDED TO THE FOLLOWING:

CHANGE OF TRADE NAME

ACRONYMS:

ACGIH AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS
CERCLA COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION AND LIABILITY ACT
ADMINISTERED BY EPA
DOT U.S. DEPARTMENT OF TRANSPORTATION
HCS OSHA 29 CFR 1910.1200
IARC INTERNATIONAL AGENCY FOR RESEARCH ON CANCER
IATA INTERNATIONAL AIR TRANSPORTATION ASSOCIATION
LD50 LETHAL DOSE 50% OF ANIMALS
NTP NATIONAL TOXICOLOGY PROGRAM
OSHA OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, U.S. DEPARTMENT OF LABOR
RCRA RESOURCE CONSERVATION AND RECOVERY ACT ADMINISTERED BY EPA
RTK RIGHT TO KNOW
SARA SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT OF 1986.
TSCA TOXIC SUBSTANCES CONTROL ACT
TWA TIME-WEIGHTED AVERAGE CONCENTRATION FOR A NORMAL 8-HOUR WORKDAY AND A
40-HOUR WORKWEEK TO WHICH NEARLY ALL WORKERS MAY BE REPEATEDLY EXPOSED,
DAY AFTER DAY, WITHOUT ADVERSE EFFECT.

TO THE BEST OF OUR KNOWLEDGE, THE INFORMATION CONTAINED HEREIN IS ACCURATE.
HOWEVER, NEITHER BAXTER HEALTHCARE CORPORATION NOR ANY OF ITS DIVISIONS OR
SUBSIDIARIES ASSUMES ANY LEGAL RESPONSIBILITY FOR USE OR RELIANCE UPON THIS
INFORMATION. FINAL DETERMINATION OF SUITABILITY OF ANY MATERIAL IS THE SOLE
RESPONSIBILITY OF THE USER. ALL MATERIALS MAY PRESENT UNKNOWN HAZARDS AND SHOULD
BE USED WITH CAUTION. ALTHOUGH CERTAIN HAZARDS ARE DESCRIBED HEREIN, WE CANNOT
GUARANTEE THAT THESE ARE THE ONLY HAZARDS THAT EXIST.

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