

BRISTOL-MYERS SQUIBB, PHARMACEUTICAL GROUP,
P.O. BOX 191, NEW BRUNSWICK, NJ 08903
EMERGENCY CONTACTS:

DATE: 2-28-92

DR. E. HAYES (TOXICOLOGY) (908) 519-2385 CHEMTREC (800) 424-9300

THE INFORMATION BELOW IS BELIEVED TO BE ACCURATE AND REPRESENTS THE BEST INFORMATION CURRENTLY AVAILABLE. HOWEVER, WE MAKE NO WARRANTY EXPRESS OR IMPLIED, WITH RESPECT TO SUCH INFORMATION, AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE.

SUBSTANCE IDENTIFICATION

SUBSTANCE: KANTREX INJECTION CAS NUMBER 25389-94-0* RTECS NZ3225030*

OTHER NAMES: KANAMYCIN SULFATE INJECTION (500 MG PER 2 ML; 1 G PER 3 ML)

MOLECULAR FORMULA: C18H36N4O11.H2O4S* MW: 582.66*

* INFORMATION APPLIES ONLY TO KANAMYCIN SULFATE

COMPONENTS

SUBSTANCE	WT%	HAZARD	EXPOSURE LIMIT
KANAMYCIN SULFATE SENSITIZER	25 - 36 EXPOSURE GUIDELINE)	POTENT DRUG,	0.3 MG/M3 (BMS
PURIFIED WATER USP	>1	NONE	NONE
SODIUM CITRATE	>1	POSSIBLE IRRITANT	NONE

PRESENT AT < 1% OR USED FOR PH ADJUSTMENT:
SULFURIC ACID; SODIUM BISULFITE

PHYSICAL DATA

APPEARANCE: CLEAR AQUEOUS SOLUTION	ODOR: NOT REMARKABLE
MELTING POINT: APPROX. 0 DEGREES C	BOILING POINT: APPROX. 100 DEGREES C
VAPOR PRESSURE: SIMILAR TO WATER	PH: 4.4 - 4.6
SOLUBILITY IN WATER: MISCIBLE	

FIRE AND EXPLOSION DATA

FLASH POINT: NOT AVAILABLE FLAMMABILITY LIMITS: NOT AVAILABLE

EXTINGUISHING MEDIA: USE WATER.

AS WITH ALL FIRES, EVACUATE PERSONNEL TO SAFE AREA. WHEN THIS MATERIAL IS INVOLVED IN A FIRE A SELF-CONTAINED BREATHING APPARATUS AND FULL PROTECTIVE CLOTHING SHOULD BE WORN BY FIREFIGHTERS. USE WATER TO KEEP FIRE-EXPOSED CONTAINERS COOL. FIGHT FIRE FROM MAXIMUM SAFE DISTANCE. DIVERT RUNOFF TO A SAFE AREA. SEE REACTIVITY DATA.

REACTIVITY DATA

STABILITY: STABLE UNDER NORMAL CONDITIONS
HAZARDOUS POLYMERIZATION: WILL NOT OCCUR
DECOMPOSITION: THERMAL DECOMPOSITION OR BURNING MAY PRODUCE NOXIOUS PRODUCTS INCLUDING: CO, CO2, NOX, SOX.
INCOMPATIBILITY: NONE KNOWN

\$PAGE

KANTREX INJECTION

PAGE 2 OF 4

SPILL, LEAK & DISPOSAL PROCEDURES

SPILL: WEARING SUITABLE PROTECTIVE CLOTHING, ABSORB LIQUID ONTO APPROPRIATE

ABSORBENT MATERIAL AND PLACE INTO A CONTAINER FOR DISPOSAL. LATEX GLOVES AND EYE PROTECTION SHOULD BE WORN AS A MINIMUM PRECAUTION. ADDITIONAL PROTECTIVE CLOTHING/EQUIPMENT MAY BE NEEDED DEPENDING ON THE EXTENT OF THE SPILL. THE SPILL AREA SHOULD BE VENTILATED AND DECONTAMINATED AFTER MATERIAL HAS BEEN PICKED UP.

DISPOSAL: DISPOSE OF IN ACCORDANCE WITH ALL LOCAL, STATE AND FEDERAL REGULATIONS OR WITH THE REGULATIONS OF THE COUNTRY IN WHICH THE MATERIAL IS USED.

HEALTH EFFECTS & FIRST AID

EXPOSURE GUIDELINE FOR KANAMYCIN SULFATE: OSHA AND ACGIH HAVE NOT ESTABLISHED PEL'S OR TLV'S FOR KANAMYCIN SULFATE. BRISTOL-MYERS SQUIBB HAS ESTABLISHED AN EXPOSURE GUIDELINE OF 0.3 MG/M3 OF AIR (FREE BASE, 8 HOUR TWA) FOR OCCUPATIONAL EXPOSURE TO KANAMYCIN SULFATE. PROVIDED THAT INGESTION AND SKIN CONTACT ARE AVOIDED, ADHERENCE TO THE EXPOSURE GUIDELINE SHOULD PROTECT EMPLOYEES AGAINST THE PHARMACOLOGICAL AND ADVERSE/TOXIC EFFECTS FROM INHALATION OF THIS COMPOUND. HOWEVER, IT IS NOT KNOWN WHETHER ADHERENCE TO THE EXPOSURE GUIDELINE WILL PREVENT THE DEVELOPMENT OF ALLERGIC REACTIONS IN SUSCEPTIBLE PERSONS. IT IS RECOMMENDED THAT PERSONNEL USE APPROPRIATE PROTECTIVE CLOTHING TO MINIMIZE SKIN CONTACT WITH KANAMYCIN SULFATE AND THAT PERSONS WITH ALLERGIES TO KANAMYCIN SULFATE AND/OR OTHER AMINOGLYCOSIDE ANTIBIOTICS SHOULD AVOID CONTACT WITH THIS COMPOUND.

ROUTES OF ENTRY: KANTREX INJECTION CONTAINS KANAMYCIN SULFATE, A POTENT AMINOGLYCOSIDE ANTIBIOTIC DRUG. IT IS INTENDED FOR INTRAMUSCULAR OR INTRAVENOUS INJECTION, UNDER THE CARE OF A PHYSICIAN.

ORAL: APPROXIMATELY 1% OF AN ORAL DOSE OF KANAMYCIN SULFATE MAY BE ABSORBED FROM THE GASTROINTESTINAL TRACT.

DERMAL: AMINOGLYCOSIDES ARE NOT NORMALLY ABSORBED THROUGH INTACT SKIN. HOWEVER, ABSORPTION MAY OCCUR FROM WOUNDS OR DENUDED SKIN.

INHALATION: THIS PRODUCT IS A LIQUID AND UNDER NORMAL CONDITIONS OF USE IS NOT AN INHALATION HAZARD.

SYMPTOMS OF EXPOSURE:

ORAL ROUTE: THIS FORMULATION CONTAINS KANAMYCIN SULFATE. WHEN INGESTED AT THERAPEUTIC DOSES, KANAMYCIN SULFATE CAUSED NAUSEA, VOMITING, AND DIARRHEA. PROLONGED ORAL USE OF THERAPEUTIC DOSES OF KANAMYCIN SULFATE MAY RESULT IN A SPRUE-LIKE SYNDROME WITH MALABSORPTION AND ELECTROLYTE DISTURBANCES. ALTHOUGH NOT WELL ABSORBED AFTER INGESTION, THERAPEUTIC DOSES OF KANAMYCIN SULFATE MAY RESULT IN THE ACCUMULATION OF THE DRUG TO TOXIC LEVELS IN PERSONS WITH IMPAIRED KIDNEY FUNCTION.

INHALATION ROUTE: UNDER NORMAL CONDITIONS, THIS LIQUID PRODUCT IS NOT AN INHALATION HAZARD.

DERMAL ROUTE: ALTHOUGH KANAMYCIN SULFATE IS POORLY ABSORBED FROM INTACT SKIN, APPLICATION OF LARGE DOSES TO WOUNDS OR BURNS MAY RESULT IN SYSTEMIC TOXICITY. SYMPTOMS OF SYSTEMIC TOXICITY MAY INCLUDE: HEARING LOSS, KIDNEY TOXICITY, AND NEUROMUSCULAR BLOCKADE. KANAMYCIN SULFATE IS CONSIDERED TO BE A CONTACT SENSITIZER. TOPICAL APPLICATION MAY RESULT IN ALLERGIC SKIN DISORDERS WITH SYMPTOMS INCLUDING: INFLAMMATION OF CONJUNCTIVAE, BURNING SENSATION, REDNESS,

\$PAGE

KANTREX INJECTION

PAGE 3 OF 4

HEALTH EFFECTS & FIRST AID (CONTINUED)

RASH AND ITCHING. CROSS SENSITIVITY HAS ALSO BEEN REPORTED AMONG AMINOGLYCOSIDES.

USE GLOVES AND PROTECTIVE CLOTHING. ADDITIONAL PROTECTIVE CLOTHING MAY BE NEEDED WHEN HANDLING LARGE QUANTITIES OF THIS PRODUCT OR IF THE POTENTIAL FOR SPLASHING EXISTS.

EYE CONTACT: THIS PRODUCT IS NOT EXPECTED TO BE A PRIMARY EYE IRRITANT.

HOWEVER, THIS PRODUCT CONTAINS A SENSITIZER AND EYE CONTACT MAY RESULT IN TEARING, REDNESS, SWELLING OR OTHER ALLERGIC REACTIONS. GOGGLES SHOULD BE WORN WHEN HANDLING LARGE QUANTITIES OF THIS PRODUCT.

MEDICAL CONDITIONS AGGRAVATED: HIGH DOSES OF KANAMYCIN SULFATE MAY AGGRAVATE IMPAIRED HEARING, CERTAIN KIDNEY DISORDERS, CERTAIN NEUROMUSCULAR DISORDERS, AND ALLERGIES TO AMINOGLYCOSIDES.

CARCINOGEN LISTS: IARC: NO NTP: NO OSHA: NO

TOXICITY:

KANAMYCIN SULFATE:

ACUTE ORAL LD50 (MOUSE) = 17500 MG/KG;	ACUTE IP LD50 (RAT) = 3200 MG/KG;
ACUTE IP LD50 (MOUSE) = 1648 MG/KG;	ACUTE SC LD50 (RAT) = 1700 MG/KG;
ACUTE SC LD50 (MOUSE) = 1648 MG/KG;	ACUTE IV LD50 (RAT) = 225 MG/KG;
ACUTE IV LD50 (MOUSE) = 240 MG/KG;	ACUTE IV LD50 (RABBIT) = 550 MG/KG;
ACUTE IM LD50 (MOUSE) = 1190 MG/KG.	

SEE RTECS FOR REPRODUCTIVE DATA ASSOCIATED WITH KANAMYCIN SULFATE. ADDITIONAL INFORMATION ABOUT THERAPEUTIC USE AND EFFECTS OF THIS PRODUCT MAY BE FOUND IN THE PACKAGE INSERT SUPPLIED WITH THIS PRODUCT.

FIRST AID FOR OVEREXPOSURE

EYE CONTACT: FLUSH WITH LARGE AMOUNTS OF WATER FOR 15-20 MINUTES.

SKIN CONTACT: WASH WITH SOAP AND WATER FOR 15-20 MINUTES.

INGESTION: GET MEDICAL ATTENTION IMMEDIATELY.

INHALATION: REMOVE TO FRESH AIR; IF DIFFICULTY IN BREATHING ADMINISTER OXYGEN. IF A PERSON IS NOT BREATHING ARTIFICIAL RESPIRATION CAN BE ATTEMPTED. GET MEDICAL ATTENTION IMMEDIATELY.

SPECIAL PROTECTION INFORMATION

PERSONNEL WHO HANDLE THIS SOLUTION IN A MANUFACTURING FACILITY SHOULD WEAR PROTECTIVE CLOTHING, INCLUDING IMPERMEABLE GLOVES, EYE PROTECTION, AND A GOWN. PERSONNEL WHO HANDLE THIS SOLUTION IN A NON-MANUFACTURING SETTING (E.G. AT A CLINICAL FACILITY) SHOULD WEAR IMPERMEABLE GLOVES AND EYE PROTECTION.

SPECIAL PRECAUTIONS & COMMENTS

STORE AT ROOM TEMPERATURE.

PERSONS WHO ARE ALLERGIC TO KANAMYCIN SULFATE, OTHER AMINOGLYCOSIDES, OR OTHER COMPONENTS OF THIS SUBSTANCE SHOULD AVOID CONTACT WITH THIS SUBSTANCE.

§PAGE

KANTREX INJECTION

PAGE 4 OF 4

SPECIAL PRECAUTIONS & COMMENTS (CONTINUED)

THERAPEUTIC AGENTS ARE INTENDED FOR USE UNDER DIRECTION OF A PHYSICIAN AND/OR UNDER THE CONDITIONS OF USE DESCRIBED ON THE LABEL. AS A GENERAL PRECAUTION, PERSONNEL WHO HANDLE DRUG SUBSTANCES SHOULD AVOID CONTACT (INGESTION, INHALATION, SKIN AND EYE CONTACT) WITH THESE SUBSTANCES.

THIS MATERIAL SAFETY DATA SHEET IS INTENDED FOR USE BY PERSONNEL WHO HANDLE THIS MATERIAL AS PART OF THEIR JOB RESPONSIBILITIES. IT DOES NOT ADDRESS THE THERAPEUTIC USE OF THIS MATERIAL. INFORMATION CONCERNING THE THERAPEUTIC USE OF THIS DRUG SUBSTANCE SHOULD BE OBTAINED FROM FORMULATED PRODUCT PACKAGE INSERTS AND OTHER APPROPRIATE REFERENCES.

DOT SHIPPING CLASSIFICATION: NONE

§ENDDTR: