

MSDS for selected criteria

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\$MSDSH:

\$PRVDR: ROCHE LABORATORIES

\$I.NAME: ROCHE LABORATORIES

\$DOCNO: M011849

\$TRANA: ROCEPHIN

\$REVDT: 30APR98

\$MSDST:

MATERIAL NAME: ROCEPHIN(R)

MSDS NUMBER .: M-011849.ASC

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APPROVED: 04/30/98

ROCHE LABORATORIES

A DIVISION OF HOFFMANN-LA ROCHE INC.

340 KINGSLAND STREET

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MATERIAL SAFETY DATA SHEET

SECTION 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MATERIAL NAME: ROCEPHIN(R)

RO #: 13-9904/001

CAS NUMBER: 104376-79-6

SYNONYMS: [6R-[6ALPHA,7BETA(Z)]]-7-[[(2-AMINO-4-THIAZOLYL)
(METHOXYIMINO)ACETYL]AMINO]-8-OXO-3-[[(1,2,5,6-
TETRAHYDRO-2-METHYL-5,6-DIOXO-1,2,4-TRIAZIN-3-YL)
THIO]METHYL]-5-THIA-1-AZABICYCLO[4.2.0]OCT-2-ENE-2-
CARBOXYLIC ACID DISODIUM SALT HYDRATE (2:7)

TSCA STATUS: FDA EXEMPTION - NOT ON INVENTORY.

CHEMICAL FAMILY: CEPHALOSPORIN

THERAPEUTIC CATEGORY: ANTIBACTERIAL

FORMULATIONS USED IN: ROCEPHIN(R) STERILE VIALS, ROCEPHIN(R) GALAXY(R)
CONTAINERS, ROCEPHIN(R) ADD-VANTAGE(R) SYSTEM

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT NAME	CAS NUMBER	CONCENTRATION %
CEFTRIAXONE SODIUM	104376-79-6	95

SECTION 3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

PHYSICAL STATE: CRYSTALLINE POWDER.

COLOR: WHITE TO YELLOWISH-ORANGE

ODOR: ODORLESS

DUST EXPLOSION HAZARD.

VIOLENT DECOMPOSITION CAN OCCUR WHEN HEATED OR IN A FIRE.

MAY CAUSE ALLERGIC REACTIONS.

POTENTIAL HEALTH EFFECTS

RELEVANT ROUTES OF

EXPOSURE: INHALATION, SKIN CONTACT, EYE CONTACT, INGESTION.

TARGET ORGANS: GASTROINTESTINAL SYSTEM, CENTRAL NERVOUS SYSTEM,
HEMATOPOIETIC/ BLOOD SYSTEM, RENAL SYSTEM, HEPATIC
SYSTEM, DERMAL SYSTEM.

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SECTION 3. HAZARDS IDENTIFICATION (CONTINUED. . .)

ACUTE EFFECTS

GENERAL: MAY CAUSE HEADACHES. MAY CAUSE BLOOD SYSTEM CHANGES.
MAY CAUSE GASTROINTESTINAL EFFECTS SUCH AS NAUSEA,
VOMITING, DIARRHEA, CONSTIPATION, CRAMPS, AND LOSS OF
APPETITE. MAY CAUSE HEPATIC (LIVER) SYSTEM EFFECTS.
SIGNS AND SYMPTOMS MAY INCLUDE ELEVATION OF LIVER
ENZYME LEVELS AND JAUNDICE (YELLOWING OF THE SKIN AND
EYES). MAY CAUSE RENAL (KIDNEY) SYSTEM EFFECTS SUCH AS
URINE RETENTION, INCREASE OR DECREASE IN URINE
PRODUCTION, PAINFUL URINATION, AND PRESENCE OF BLOOD IN
URINE. MAY CAUSE CENTRAL NERVOUS SYSTEM EFFECTS SUCH
AS HEADACHE, DIZZINESS, DROWSINESS, FATIGUE, AND LACK
OF MUSCULAR COORDINATION.

SKIN: MAY CAUSE ALLERGIC REACTIONS.

CHRONIC EFFECTS: NO ADVERSE EFFECTS KNOWN.

CARCINOGENICITY: NOT LISTED BY NTP, IARC, OR OSHA.
CONDITIONS

AGGRAVATED: HYPERSENSITIVITY TO PENICILLIN AND OTHER ANTIBIOTICS.
ADDITIONAL HEALTH

HAZARD INFORMATION .: SINCE THIS MATERIAL HAS BEEN SHOWN TO BE EXCRETED IN
BREAST MILK, NURSING MOTHERS SHOULD EXERCISE CAUTION
REGARDING EXPOSURE.

SECTION 4. FIRST AID MEASURES

INHALATION: REMOVE TO FRESH AIR. IF DISCOMFORT OCCURS OR PERSISTS,
GET MEDICAL ATTENTION.

SKIN CONTACT: REMOVE CONTAMINATED CLOTHING AND SHOES. WASH SKIN WITH
SOAP AND PLENTY OF WATER. IF IRRITATION OCCURS OR
PERSISTS, GET MEDICAL ATTENTION. WASH CLOTHING AND
SHOES BEFORE REUSE.

EYE CONTACT: IMMEDIATELY FLUSH EYES WITH PLENTY OF WATER. IF
IRRITATION OCCURS OR PERSISTS, GET MEDICAL ATTENTION.

INGESTION: IF LARGE QUANTITIES OF THIS MATERIAL ARE SWALLOWED, GET
MEDICAL ATTENTION IMMEDIATELY. DO NOT INDUCE VOMITING
UNLESS DIRECTED BY MEDICAL PERSONNEL. NEVER GIVE
ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON.

SECTION 5. FIRE FIGHTING MEASURES

FLASH POINT: NOT APPLICABLE
EXTINGUISHING MEDIA : WATER, CARBON DIOXIDE, DRY CHEMICAL, FOAM.
UNUSUAL FIRE AND
EXPLOSION HAZARDS ...: DUST EXPLOSION HAZARD. VIOLENT DECOMPOSITION CAN OCCUR
WHEN HEATED OR IN A FIRE. TOXIC EMISSIONS MAY BE GIVEN
OFF IN A FIRE. SEE DECOMPOSITION PRODUCTS IN SECTION
10. STABILITY AND REACTIVITY.

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SECTION 5. FIRE FIGHTING MEASURES (CONTINUED. . .)

FIRE FIGHTING

INSTRUCTIONS: WEAR NIOSH/MSHA APPROVED POSITIVE PRESSURE, SELF
CONTAINED BREATHING APPARATUS AND FULL PROTECTIVE TURN
OUT GEAR. USE CAUTION IN APPROACHING FIRE. USE WATER
TO KEEP FIRE EXPOSED CONTAINERS COOL.
ST NUMBER: 1, HARTMANN TUBE.

SECTION 6. ACCIDENTAL RELEASE MEASURES

SPILL CLEAN UP

PROCEDURES: USE PROPER PERSONAL PROTECTIVE EQUIPMENT AND CLOTHING
SPECIFIED IN SECTION 8-EXPOSURE CONTROLS/PERSONAL
PROTECTION. SHUT OFF THE SOURCE OF THE SPILL OR LEAK
IF IT IS SAFE TO DO SO. SHUT OFF ALL ELECTRICAL
EQUIPMENT IF IT IS SAFE TO DO SO. ELIMINATE POSSIBLE
IGNITION SOURCES. FOLLOW APPROPRIATE GROUNDING
PROCEDURES. SCOOP OR SHOVEL SPILLED MATERIAL INTO A
SUITABLE LABELED OPEN HEAD DRUM. SECURE THE DRUM COVER
AND MOVE THE CONTAINER TO A SAFE HOLDING AREA. MOP OR
FLUSH THE AREA WITH WATER. COLLECT WASH WITH A
NONCOMBUSTIBLE ABSORBENT MATERIAL AND TRANSFER TO
LABELED CONTAINER FOR TREATMENT AND DISPOSAL. CHECK
AREA FOR RESIDUAL MATERIAL AND REPEAT CLEAN UP IF
DETECTED.

TREATMENT AND

DISPOSAL: DECONTAMINATE EQUIPMENT. DISPOSE OF PROTECTIVE
CLOTHING WITH THE SPILLED MATERIAL. DISPOSE OF IN
ACCORDANCE WITH RECOMMENDATIONS IN SECTION 13 DISPOSAL
CONSIDERATIONS.

REPORTING

REQUIREMENTS: THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
(USEPA) HAS NOT ESTABLISHED A REPORTABLE QUANTITY (RQ)
FOR RELEASES OF THIS MATERIAL. IN NEW JERSEY, REPORT
ALL RELEASES WHICH ARE LIKELY TO ENDANGER THE PUBLIC
HEALTH, HARM THE ENVIRONMENT OR CAUSE A COMPLAINT TO
THE NJDEPE HOTLINE (1-609-292-5560) AND TO LOCAL
OFFICIALS. STATE AND LOCAL REGULATIONS VARY AND MAY
IMPOSE ADDITIONAL REPORTING REQUIREMENTS.

SECTION 7. HANDLING AND STORAGE

STORAGE TEMPERATURE

(MIN/MAX): BELOW 25 C
SHELF LIFE: 12 MONTHS

SPECIAL SENSITIVITY : HEAT. DO NOT HEAT ABOVE 50 DEGREES C. EXPOSURE TO THE FOLLOWING MAY AFFECT THE INTEGRITY OF THIS MATERIAL:
LIGHT. MOISTURE.

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SECTION 7. HANDLING AND STORAGE (CONTINUED. . .)

HANDLING & STORAGE

PRECAUTIONS: DO NOT GENERATE DUST OR EXPOSE TO IGNITION SOURCES.
GROUND AND BOND ALL TRANSFER EQUIPMENT.
MILLING/MIXING/DRYING SHOULD BE DONE AT THE LOWEST POSSIBLE TEMPERATURE UNDER VACUUM OR INERT CONDITIONS.
AVOID CONTACT WITH EYES.
AVOID PROLONGED OR REPEATED CONTACT WITH SKIN AND CLOTHING.
AVOID BREATHING DUST.
USE WITH ADEQUATE VENTILATION.
WHEN HANDLING, USE PROPER PERSONAL PROTECTIVE EQUIPMENT SPECIFIED IN SECTION 8.
WASH THOROUGHLY AFTER HANDLING.
KEEP CONTAINER TIGHTLY CLOSED WHEN NOT IN USE.
STORE IN A COOL, DRY AREA.
STORE IN LIGHT RESISTANT CONTAINERS.

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS

VENTILATION: LOCAL VENTILATION IS REQUIRED WHEN USING THIS MATERIAL.
USE IN A LAB HOOD.

PERSONAL PROTECTION

RESPIRATOR TYPE(S) .: NEGATIVE PRESSURE AIR PURIFYING, HALF FACE, TOXIC DUST/MIST/FUME HIGH EFFICIENCY FILTER.
CONDITIONS FOR USE .: RESPIRATORY PROTECTION IS RECOMMENDED FOR DUSTY OPERATIONS. OSHA CONSIDERS EFFECTIVE ENGINEERING CONTROLS TO BE THE PRIMARY MEANS TO CONTROL WORKER EXPOSURE. RESPIRATORY PROTECTION SHOULD NOT SUBSTITUTE FOR FEASIBLE ENGINEERING CONTROLS. WHENEVER RESPIRATORY PROTECTION IS USED, A COMPLETE RESPIRATOR PROGRAM SHOULD BE DEVELOPED IN ACCORDANCE WITH OSHA SUBPART I (29CFR1910.134) REQUIREMENTS.
GLOVE MATERIALS: ANY PLASTIC OR RUBBER GLOVE.
CONDITIONS FOR USE .: GLOVES ARE REQUIRED IF THERE IS A POTENTIAL FOR SKIN CONTACT.
SKIN PROTECTION: USE PROTECTIVE CLOTHING (LAB COATS, DISPOSABLE COVERALLS, ETC.) IN BOTH PRODUCTION AND LABORATORY AREAS. CONSULT THE PROTECTIVE CLOTHING MANUFACTURER, SUPPLIER AND/OR INDUSTRIAL HYGIENIST.
EYE PROTECTION: SAFETY GLASSES REQUIRED, SAFETY GOGGLES RECOMMENDED.

OTHER CONTROL MEASURES

ADDITIONAL

PROTECTIVE MEASURES : PERIODICALLY MONITOR FOR MATERIALS HAVING EXPOSURE LIMITS. WORK CLOTHING SHOULD BE REMOVED IN A CHANGEROOM ON SITE AND LAUNDERED PROFESSIONALLY.
EMPLOYEES SHOULD SHOWER AND CHANGE INTO STREET CLOTHES

BEFORE LEAVING THE FACILITY. PROVIDE SAFETY SHOWERS
AND EYEWASH STATIONS IN THE WORK AREA. PREVENT THE
ACCUMULATION OF DUST IN THE WORK AREA BY THOROUGH
PERIODIC CLEANING OF THE AREA.

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SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION (CONTINUED. . .)

EXPOSURE LIMITS

ROCEPHIN(R)

ROCHE IOEL: 0.0200 MG/M3 8 HR. TIME WEIGHTED AVERAGE.

ROCHE IOEL: 0.0600 MG/M3 SHORT TERM EXPOSURE LIMIT.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE CRYSTALLINE POWDER.

COLOR WHITE TO YELLOWISH-ORANGE

ODOR ODORLESS

MOLECULAR WEIGHT 661.59

CHEMICAL FORMULA C18H16N8NA2O7S3.3.5H2O

PURE/MIXTURE PURE.

MELTING POINT >155 C

H2O SOLUBILITY 470 G/L; APPRECIABLY SOLUBLE (>10% BY WEIGHT).

SOLUBILITY - OTHER .. VERY SLIGHTLY SOLUBLE IN ETHANOL AND SPARINGLY SOLUBLE
IN METHANOL

BULK DENSITY 0.3 TO 0.4 KG/L

SECTION 10. STABILITY AND REACTIVITY

STABILITY NORMALLY STABLE BUT MAY BECOME UNSTABLE AT ELEVATED
TEMPERATURES OR REACTS WITH WATER, RELEASING SOME
ENERGY BUT NOT VIOLENTLY.

CONDITIONS TO AVOID : ELEVATED TEMPERATURES
SOURCES OF HEAT
DUST ACCUMULATION
AIRBORNE DUST
SOURCES OF IGNITION

INCOMPATIBILITY -

MATERIALS TO AVOID .. OXIDIZING AGENTS.

DECOMPOSITION

PRODUCTS CARBON MONOXIDE, CARBON DIOXIDE, OXIDES OF NITROGEN,
OXIDES OF SULFUR

POLYMERIZATION NO

CONDITIONS OF

POLYMERIZATION WILL NOT OCCUR.

SECTION 11. TOXICOLOGICAL INFORMATION

CEFTRIAXONE SODIUM

ACUTE ORAL, SINGLE DOSE, RAT: >10000 MG/KG

SUMMARY: ACUTE ORAL LD50 (RAT) IS GREATER THAN 10,000 MG/KG BODY WEIGHT

(LIMIT TEST) AT 7 DAYS UNDER THE STUDY CONDITIONS UTILIZED. NO DEATHS OCCURRED DURING THE OBSERVATION PERIOD.

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SECTION 11. TOXICOLOGICAL INFORMATION (CONTINUED. . .)

REPRODUCTIVE INTRAVENOUS, RAT

SUMMARY: NO ADVERSE EFFECTS ON GONADAL FUNCTION, FERTILITY, CONCEPTION RATE, GESTATION OR PARTURITION WERE OBSERVED IN RATS TREATED WITH INTRAVENOUS DOSES UP TO 586 MG/KG/DAY FROM DAY 17 THROUGH DAY 21 OF GESTATION. NO DEVELOPMENTAL OR BEHAVIORAL EFFECTS WERE OBSERVED IN THE OFFSPRING OF TREATED RATS, UNDER THE STUDY CONDITIONS UTILIZED.

TERATOGENICITY INTRAVENOUS, MONKEY

SUMMARY: NO EVIDENCE OF EMBRYOTOXICITY OR TERATOGENICITY WAS OBSERVED IN THE OFFSPRING OF MONKEYS TREATED WITH INTRAVENOUS DOSES UP TO 84 MG/KG/DAY DURING GESTATION DAYS 21 THROUGH 31 OR 32 THROUGH 45, UNDER THE STUDY CONDITIONS UTILIZED.

TERATOGENICITY INTRAVENOUS, MOUSE

SUMMARY: NO EVIDENCE OF EMBRYOTOXICITY OR TERATOGENICITY WAS OBSERVED IN THE OFFSPRING OF MICE TREATED WITH INTRAVENOUS DOSES UP TO 625 MG/KG/DAY FROM DAY 6 THROUGH DAY 15 OF GESTATION, UNDER THE STUDY CONDITIONS UTILIZED.

TERATOGENICITY INTRAVENOUS, RAT

SUMMARY: NO EVIDENCE OF EMBRYOTOXICITY OR TERATOGENICITY WAS OBSERVED IN THE OFFSPRING OF RATS TREATED WITH INTRAVENOUS DOSES UP TO 586 MG/KG/DAY FROM DAY 7 THROUGH DAY 17, UNDER THE STUDY CONDITIONS UTILIZED.

MUTAGENICITY

SUMMARY: NO EVIDENCE OF MUTAGENICITY WAS OBSERVED IN THE FOLLOWING IN VITRO ASSAYS: AMES TEST WITH OR WITHOUT METABOLIC ACTIVATION, "TREAT AND PLATE" ASSAY AND HUMAN LYMPHOCYTE CHROMOSOMAL ABERRATION ASSAY UNDER THE STUDY CONDITIONS UTILIZED.

MUTAGENICITY

SUMMARY: NO EVIDENCE OF MUTAGENICITY WAS OBSERVED IN THE IN VIVO MICRONUCLEUS ASSAY UNDER THE STUDY CONDITIONS UTILIZED.

SECTION 12. ECOLOGICAL INFORMATION

ROCEPHIN(R)

NO OBSERVABLE EFFECT LEVEL, TROUT : >1000 MG/L

SUMMARY: THIS MATERIAL IS CLASSIFIED AS SLIGHTLY TOXIC TO FISH (RAINBOW TROUT): NEC > 1000 MG/L UNDER THE STUDY CONDITIONS UTILIZED. THIS MATERIAL IS A HIGHLY ACTIVE SUBSTANCE.

AEROBIC BIODEGRADATION (H2O)

SUMMARY: THIS MATERIAL IS NOT BIODEGRADABLE (ZAHN-WELLENS-TEST, MITI-TEST II, BOD5) UNDER THE STUDY CONDITIONS UTILIZED.

MICROBIAL INHIBITORY CONCENTRATION, MICROBES (NONSPECIFIC) : 10.0 MG/L

SUMMARY: THIS MATERIAL IS CLASSIFIED AS MODERATELY TO HIGHLY TOXIC FOR MICROORGANISMS: NEC 10 MG/L (FOR NON-ADAPTED ACTIVATED SLUDGE), UNDER THE STUDY CONDITIONS UTILIZED.

N-OCTANOL/WATER PARTITION COEFFICIENT : 0.0300

SUMMARY: CEFTRIAXONE PARTITION COEFFICIENT OCTANOL/WATER POW = 0.025 (PH=2.0).

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SECTION 13. DISPOSAL CONSIDERATIONS

DISPOSAL

RECOMMENDATIONS ..::: THIS MATERIAL IS SUITABLE FOR INCINERATION. THESE RECOMMENDATIONS ARE BASED ON THE PRODUCT AS SHIPPED. USE, PROCESSING, ALTERATION OR CONTAMINATION MAY AFFECT THESE DISPOSAL RECOMMENDATIONS. STATE, LOCAL OR SITE RESTRICTIONS AFFECTING THE AVAILABLE PROPER DISPOSAL OPTIONS MAY VARY.

RCRA WASTE # ..::: NOT REGULATED UNDER RCRA

EMPTY CONTAINERS ...: EMPTY CONTAINERS MUST BE TRIPLE RINSED PRIOR TO DISPOSAL, RECYCLING, OR REUSE.

SECTION 14. TRANSPORTATION INFORMATION

ENFORCEMENT AGENCY ..: US DEPT. OF TRANSPORTATION
COUNTRY/COMMUNITY ...: USA
PROPER SHIP. NAME ...: NON-REGULATED

ENFORCEMENT AGENCY ..: INTERNATIONAL AIR TRANSPORT ASSOCIATION
COUNTRY/COMMUNITY ...: INTERNATIONAL
PROPER SHIP. NAME ...: NON-REGULATED

SECTION 15. REGULATORY INFORMATION

NO REGULATORY INFORMATION AVAILABLE ON THIS MATERIAL.

SECTION 16. OTHER INFORMATION

APPROVAL INFORMATION

PREPARER ..::: ANNETTE BUCCA-JANACEK
APPROVER ..::: CORPORATE ENVIRONMENTAL & SAFETY AFFAIRS
APPROVAL DATE ..::: 04/30/98
PREVIOUS APPROVAL
DATE ..::: 06/27/95
REASON FOR ISSUE ...: THREE YEAR REVISION.

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\$ENDTR: