

MATERIAL NAME: MATULANE(R) CAPSULE MIX (50 MG)
MATERIAL CODE: 79993
MSDS NUMBER .: M-012047.ASC

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APPROVED: 10/31/95

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MATERIAL SAFETY DATA SHEET

SECTION 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MATERIAL NAME: MATULANE(R) CAPSULE MIX (50 MG)
INVENTORY CODE: 79993
TSCA STATUS: FDA EXEMPTION - NOT ON INVENTORY.
THERAPEUTIC CATEGORY: ANTINEOPLASTIC

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT NAME	CAS NUMBER	CONCENTRATION %
STARCH	9005-25-8	21 APROX.
PROCARBAZINE HYDROCHLORIDE	366-70-1	18 APROX.
TALC	14807-96-6	8 APROX.

SECTION 3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

PHYSICAL STATE: POWDER.
COLOR: WHITE TO SLIGHTLY YELLOW

MAY CAUSE CANCER BASED ON ANIMAL STUDIES.
MAY CAUSE BIRTH DEFECTS BASED ON ANIMAL DATA.
MAY CAUSE MALE REPRODUCTIVE SYSTEMS EFFECTS BASED ON ANIMAL DATA.
MAY CAUSE SKIN IRRITATION.

POTENTIAL HEALTH EFFECTS

RELEVANT ROUTES OF
EXPOSURE: INHALATION, SKIN CONTACT, EYE CONTACT, INGESTION.
TARGET ORGANS: RESPIRATORY SYSTEM, GASTROINTESTINAL SYSTEM, CENTRAL
NERVOUS SYSTEM, HEMATOPOIETIC/ BLOOD SYSTEM, MALE
REPRODUCTIVE SYSTEM/ PROSTATE, DERMAL SYSTEM, OCULAR
SYSTEM.

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SECTION 3. HAZARDS IDENTIFICATION (CONTINUED. . .)

ACUTE EFFECTS

GENERAL: MAY CAUSE BLOOD SYSTEM CHANGES. MAY CAUSE
GASTROINTESTINAL EFFECTS SUCH AS NAUSEA, VOMITING,
DIARRHEA, CONSTIPATION, CRAMPS, AND LOSS OF APPETITE.

MAY CAUSE CENTRAL NERVOUS SYSTEM EFFECTS SUCH AS HEADACHE, DIZZINESS, DROWSINESS, FATIGUE, AND LACK OF MUSCULAR COORDINATION. MAY CAUSE RESPIRATORY EFFECTS SUCH AS DIFFICULTY IN BREATHING, COUGHING, WHEEZING, IRRITATION (INFLAMMATION) AND RESPIRATORY ARREST. MAY CAUSE MUSCULOSKELETAL EFFECTS SUCH AS MUSCLE WEAKNESS OR PAIN AND SKELETAL ABNORMALITIES. 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 ALLERGIC REACTIONS.

SKIN: MAY CAUSE SKIN IRRITATION.
EYE: MAY CAUSE EYE IRRITATION. MAY CAUSE IMPAIRMENT OF VISION.

CHRONIC EFFECTS

GENERAL: MAY CAUSE HYPERPIGMENTATION OF THE SKIN. CHRONIC EXPOSURE TO LARGE AMOUNTS OF THIS MATERIAL MAY CAUSE SCARRING OF THE LUNGS, SHORTNESS OF BREATH, COUGH, AND POSSIBLE DISABILITY OR DEATH. MAY CAUSE HALLUCINATIONS. MAY CAUSE CONFUSION AND DISORIENTATION. MAY CAUSE PERIPHERAL NEUROPATHY (DETERIORATION OF NERVES AND NERVE TISSUE).

CARCINOGENICITY: FORMULATION NOT LISTED BY NTP, IARC, OR OSHA. MAY CAUSE CANCER BASED ON ANIMAL STUDIES. MAY CAUSE LUNG CANCER BASED ON ANIMAL DATA. MAY CAUSE BREAST CANCER BASED ON ANIMAL DATA. MAY CAUSE LEUKEMIA BASED ON ANIMAL DATA. MAY CAUSE NERVOUS SYSTEM CANCER BASED ON ANIMAL DATA.

PROCARBAZINE HYDROCHLORIDE

NTP REASONABLY ANTICIPATED TO BE CARCINOGENIC.
IARC GR2A PROBABLY CARCINOGENIC TO HUMANS.

REPRODUCTIVE

TOXICITY: PROCARBAZINE HYDROCHLORIDE MAY CAUSE BIRTH DEFECTS BASED ON ANIMAL DATA. MAY CAUSE MALE REPRODUCTIVE SYSTEMS EFFECTS BASED ON ANIMAL DATA. SINCE THIS MATERIAL MAY AFFECT REPRODUCTIVE CAPABILITIES AND THE DEVELOPING FETUS, FEMALES AND MALES PLANNING TO HAVE A CHILD AND PREGNANT WOMEN SHOULD EXERCISE CAUTION REGARDING POTENTIAL EXPOSURE. IT IS ALSO ADVISABLE FOR NURSING MOTHERS TO EXERCISE CAUTION REGARDING EXPOSURE.

CONDITIONS

AGGRAVATED: HYPERSENSITIVITY TO THIS MATERIAL. LIVER CONDITIONS AND/OR IMPAIRED LIVER FUNCTION. KIDNEY CONDITIONS AND/OR IMPAIRED RENAL FUNCTION. BLOOD SYSTEM DISORDERS. RESPIRATORY SYSTEM CONDITIONS.

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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 ..: TOXIC EMISSIONS MAY BE GIVEN OFF IN A FIRE.
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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

SPILL CLEAN UP
PROCEDURES: REVIEW SECTION 3-HAZARDS IDENTIFICATION, AND SECTION
8-EXPOSURE CONTROLS/PERSONAL PROTECTION BEFORE
PROCEEDING WITH THE CLEAN UP. SHUT OFF THE SOURCE OF
THE SPILL OR LEAK IF IT IS SAFE TO DO SO. SCOOP OR
SHOVEL SPILLED MATERIAL INTO A SUITABLE LABELED
CONTAINER WITH A TIGHT FITTING LID. SECURE THE
CONTAINER LID WITH AN AIRTIGHT SEAL SUCH AS TAPE AND
MOVE THE CONTAINER TO A SAFE HOLDING AREA. CLEAN SPILL
AREA THOROUGHLY. 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.

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SECTION 6. ACCIDENTAL RELEASE MEASURES (CONTINUED. . .)

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): ROOM TEMPERATURE
HANDLING & STORAGE
PRECAUTIONS: AVOID CONTACT WITH EYES, SKIN AND CLOTHING.
AVOID BREATHING DUST.
AVOID CREATING DUST WHEN HANDLING.
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 DRY AREA AT ROOM TEMPERATURE.

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS

VENTILATION: LOCAL VENTILATION IS REQUIRED WHEN USING THIS MATERIAL.

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.

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

OTHER CONTROL MEASURES

ADMINISTRATIVE

CONTROLS: POST THE WORK AREA AND LIMIT ACCESS TO AUTHORIZED PERSONNEL ONLY.

ADDITIONAL

PROTECTIVE MEASURES : WORK CLOTHING SHOULD BE REMOVED IN A CHANGEROOM ON SITE AND LAUNDERED PROFESSIONALLY. LAUNDRY CONTAMINATED CLOTHING SEPARATELY. 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.

EXPOSURE LIMITS

STARCH

ACGIH TLV: 10.0 MG/M3 TIME WEIGHTED AVERAGE.

OSHA PEL: 5.00 MG/M3 TIME WEIGHTED AVERAGE, RESPIRABLE FRACTION.

OSHA PEL: 15.0 MG/M3 TIME WEIGHTED AVERAGE, TOTAL DUST.

NIOSH REL: 5.00 MG/M3 TIME WEIGHTED AVERAGE, RESPIRABLE FRACTION.

NIOSH REL: 10.0 MG/M3 TIME WEIGHTED AVERAGE, TOTAL DUST.

TALC

ACGIH TLV: 2.00 MG/M3 TIME WEIGHTED AVERAGE, RESPIRABLE FRACTION.

OSHA PEL: 2.00 MG/M3 TIME WEIGHTED AVERAGE, RESPIRABLE FRACTION.

NIOSH REL: 2.00 MG/M3 TIME WEIGHTED AVERAGE, RESPIRABLE FRACTION.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE: POWDER.

COLOR: WHITE TO SLIGHTLY YELLOW

PURE/MIXTURE: MIXTURE.

SECTION 10. STABILITY AND REACTIVITY

STABILITY: NORMALLY STABLE EVEN UNDER FIRE EXPOSURE CONDITIONS AND NOT WATER REACTIVE
CONDITIONS TO AVOID : DUST ACCUMULATION
AIRBORNE DUST
SOURCES OF IGNITION
INCOMPATIBILITY -
MATERIALS TO AVOID .: UNKNOWN.
POLYMERIZATION: NO
CONDITIONS OF
POLYMERIZATION: WILL NOT OCCUR.

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SECTION 11. TOXICOLOGICAL INFORMATION

PROCARBAZINE HYDROCHLORIDE
ACUTE ORAL, RAT: 785 MG/KG
SUMMARY: ACUTE ORAL LD50 (RAT) OF 785 MG/KG BODY WEIGHT AT 5 DAYS
CLASSIFIES THIS MATERIAL AS MODERATELY TOXIC ORALLY UNDER THE STUDY
CONDITIONS UTILIZED.

IRRITATION EYE, RABBIT
SUMMARY: A STUDY WITH NEW ZEALAND WHITE RABBITS PRODUCED SCORES OF 15.0, 1.7, 1.0, 1.0, AND 0.0 AT 1 DAY, 2 DAYS, 3 DAYS, 4 DAYS AND 7 DAYS POST-INSTILLATION, RESPECTIVELY, INDICATING THAT THIS MATERIAL WAS MILDLY IRRITATING TO THE EYES OF RABBITS UNDER THE STUDY CONDITIONS UTILIZED.

IRRITATION SKIN, RABBIT
SUMMARY: A SCORE OF 2.8 FOR BOTH INTACT AND ABRADED SKIN INDICATES THAT THIS MATERIAL WAS MODERATELY IRRITATING TO THE SKIN OF RABBITS UNDER THE STUDY CONDITIONS UTILIZED.

CARCINOGENICITY INTRAPERITONEAL, MOUSE
SUMMARY: PROCARBAZINE HYDROCHLORIDE ADMINISTERED BY REPEATED INTRAPERITONEAL INJECTIONS PRODUCED MALIGNANT TUMORS OF THE NERVOUS SYSTEM AND BLOOD SYSTEM. ORAL ADMINISTRATION PRODUCED PULMONARY TUMORS AND LEUKEMIAS IN MICE.

CARCINOGENICITY INTRAPERITONEAL, RABBIT
SUMMARY: PROCARBAZINE HYDROCHLORIDE ADMINISTERED BY REPEATED INTRAPERITONEAL INJECTION PRODUCED MALIGNANT TUMORS OF THE NERVOUS SYSTEM, BLOOD SYSTEM AND ADENOCARCINOMAS OF THE MAMMARY GLAND IN RATS. REPEATED INTRAVENOUS INJECTIONS INDUCED MALIGNANT TUMORS IN DIFFERENT ORGANS OF RATS. ORAL ADMINISTRATION ALSO PRODUCED MAMMARY TUMORS IN RATS.

CARCINOGENICITY MONKEY
SUMMARY: STUDIES IN MONKEYS ALSO SUGGEST THAT PROCARBAZINE HYDROCHLORIDE PRODUCED LEUKEMIA AND MALIGNANT NEOPLASMS (SOLID TUMORS) WHEN ADMINISTERED BY MULTIPLE ROUTES.

REPRODUCTIVE MONKEY
SUMMARY: MALE REPRODUCTIVE SYSTEM EFFECTS, E.G., TESTICULAR ATROPHY AND NO EVIDENCE OF SPERMATOGENESIS, WERE OBSERVED IN THREE DIFFERENT SPECIES OF MONKEYS.

REPRODUCTIVE MOUSE
SUMMARY: SPERMATOCYTE DEATH WAS OBSERVED IN MICE TREATED WITH PROCARBAZINE HCL. OTHER STUDIES WITH MALE MICE HAVE SHOWN THAT THIS MATERIAL AFFECTS NORMAL DEVELOPMENT OF ALL SPERMATOGENIC CELL TYPES EXCEPT FOR LATE SPERMATIDS AND MATURE SPERMATOZOA AND SIGNIFICANTLY DECREASED FERTILITY THROUGHOUT A 55-DAY PERIOD.

REPRODUCTIVE RAT

SUMMARY: SPERMATOCYTE DEATH WAS OBSERVED IN RATS TREATED WITH PROCARBAZINE HYDROCHLORIDE.

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SECTION 11. TOXICOLOGICAL INFORMATION (CONTINUED. . .)

TERATOGENICITY INTRAPERITONEAL, SINGLE DOSE, RAT

SUMMARY: SINGLE INTRAPERITONEAL INJECTIONS OF PROCARBAZINE HYDROCHLORIDE IN PREGNANT RATS OF 5-550 MG/KG CAUSED FETAL DEATHS AND/OR FETAL MALFORMATIONS, E.G., TAIL AND APPENDAGE DEFECTS, BRAIN INJURY, FACIAL CLEFTS, CLEFT PALATES, AND SHORTENED JAWS.

MUTAGENICITY

SUMMARY: PROCARBAZINE HYDROCHLORIDE HAS BEEN SHOWN TO BE MUTAGENIC IN A VARIETY OF BACTERIAL, INSECT, AND MAMMALIAN TEST SYSTEMS.

SECTION 12. ECOLOGICAL INFORMATION

NO ECOLOGICAL DATA AVAILABLE ON THIS MATERIAL.

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

LAW/REGULATION: SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
PROPOSITION 65

COMMON NAME: PROP 65

ENFORCEMENT AGENCY .: CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

GOVERNING AUTHORITY : CALIFORNIA, USA

CRITERIA MET: FORMULATION CONTAINS PROCARBAZINE HYDROCHLORIDE WHICH IS KNOWN TO THE STATE TO CAUSE CANCER AND REPRODUCTIVE TOXICITY.

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SECTION 15. REGULATORY INFORMATION (CONTINUED. . .)

LAW/REGULATION: HAZARDOUS CHEMICAL REPORTING: COMMUNITY RIGHT-TO-KNOW
40CFR370
COMMON NAME: SARA TITLE III SECTION 312 - HAZARDOUS CHEMICAL
INVENTORY
ENFORCEMENT AGENCY .: ENVIRONMENTAL PROTECTION AGENCY (EPA)
GOVERNING AUTHORITY : USA
CRITERIA MET: ACUTE

SECTION 16. OTHER INFORMATION

ADDITIONAL
INFORMATION: NFPA RATING: THESE RATINGS ARE BASED ON NFPA CODE 704
AND ARE INTENDED FOR USE BY EMERGENCY PERSONNEL TO
DETERMINE THE IMMEDIATE HAZARDS OF A MATERIAL.
...HEALTH 2
...FIRE 0
...REACTIVITY 0

APPROVAL INFORMATION
PREPARER: HESHAM M. SOLIMAN
APPROVER: CORPORATE ENVIRONMENTAL & SAFETY AFFAIRS
APPROVAL DATE: 10/31/95
REASON FOR ISSUE ...: NEW

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