

MATERIAL NAME: LIBRIUM(R) CAPSULE MIX (10 MG)
MATERIAL CODE: 76201
MSDS NUMBER : M-012380.ASC

PAGE: 1
APPROVED: 02/28/96

ROCHE PRODUCTS INC.
A DIVISION OF HOFFMANN-LA ROCHE INC.
340 KINGSLAND STREET
NUTLEY, NJ 07110-1199

EMERGENCY: (800) 827-6243
CHEMTREC: (800)-424-9300
INFORMATION: (800) 526-6367

MATERIAL SAFETY DATA SHEET

SECTION 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MATERIAL NAME: LIBRIUM(R) CAPSULE MIX (10 MG)
INVENTORY CODE: 76201
TSCA STATUS: FDA EXEMPTION - NOT ON INVENTORY.
THERAPEUTIC CATEGORY: SEDATIVE (HYPNOTIC)

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

| INGREDIENT NAME | CAS NUMBER | CONCENTRATION % |
|--------------------------------|------------|-----------------|
| STARCH | 9005-25-8 | 15 APROX. |
| TALC | 14807-96-6 | 2.44 |
| CHLORDIAZEPoxide HYDROCHLORIDE | 438-41-5 | 2-13 APROX. |

SECTION 3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW
PHYSICAL STATE: POWDER.

POSSIBLE DUST EXPLOSION HAZARD BASED ON INFORMATION ON RELATED MATERIALS.
VIOLENT DECOMPOSITION MAY OCCUR WHEN HEATED OR IN A FIRE BASED ON INFORMATION
ON RELATED MATERIALS.
CAUSES CENTRAL NERVOUS SYSTEM DEPRESSION.

POTENTIAL HEALTH EFFECTS
RELEVANT ROUTES OF
EXPOSURE: INHALATION, SKIN CONTACT, EYE CONTACT, INGESTION.
TARGET ORGANS: RESPIRATORY SYSTEM, CENTRAL NERVOUS SYSTEM,
HEMATOPOIETIC/ BLOOD SYSTEM, HEPATIC SYSTEM.

MATERIAL NAME: LIBRIUM(R) CAPSULE MIX (10 MG)
MATERIAL CODE: 76201
MSDS NUMBER : M-012380.ASC

PAGE: 2
APPROVED: 02/28/96

SECTION 3. HAZARDS IDENTIFICATION (CONTINUED. . .)

ACUTE EFFECTS

GENERAL: MAY CAUSE MUCOUS MEMBRANE IRRITATION (INFLAMMATION).
MAY CAUSE CENTRAL NERVOUS SYSTEM EFFECTS SUCH AS
HEADACHE, DIZZINESS, DROWSINESS, FATIGUE, AND LACK OF
MUSCULAR COORDINATION. CAUSES CENTRAL NERVOUS SYSTEM
DEPRESSION. MAY CAUSE BLOOD SYSTEM CHANGES. 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
RESPIRATORY EFFECTS SUCH AS DIFFICULTY IN BREATHING,
COUGHING, WHEEZING, IRRITATION (INFLAMMATION) AND
RESPIRATORY ARREST.

SKIN: MAY CAUSE SKIN IRRITATION.
EYE: MAY CAUSE EYE IRRITATION.

CHRONIC EFFECTS

GENERAL: MAY CAUSE LACK OF MUSCLE COORDINATION.

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

REPRODUCTIVE

TOXICITY: CHLORDIAZEPoxide HYDROCHLORIDE
AN INCREASED RISK OF CONGENITAL MALFORMATIONS
ASSOCIATED WITH THE USE OF MINOR TRANQUILIZERS, SUCH AS
DIAZEPAM AND CHLORDIAZEPoxide, DURING THE FIRST
TRIMESTER OF PREGNANCY HAS BEEN SUGGESTED. SINCE THIS
MATERIAL MAY AFFECT THE DEVELOPING FETUS, FEMALES
PLANNING TO HAVE A CHILD AND PREGNANT WOMEN SHOULD
EXERCISE CAUTION REGARDING 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. RESPIRATORY SYSTEM
CONDITIONS.

ADDITIONAL HEALTH

HAZARD INFORMATION : THIS MATERIAL MAY CAUSE IMPAIRMENT OF MENTAL AND/OR
PHYSICAL ABILITIES WHICH ARE REQUIRED TO PERFORM
HAZARDOUS TASKS, SUCH AS OPERATING MACHINERY OR DRIVING
A MOTOR VEHICLE.

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.

MATERIAL NAME: LIBRIUM(R) CAPSULE MIX (10 MG)

PAGE: 3

MATERIAL CODE: 76201

APPROVED: 02/28/96

MSDS NUMBER : M-012380.ASC

SECTION 4. FIRST AID MEASURES (CONTINUED. . .)

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 : POSSIBLE DUST EXPLOSION HAZARD BASED ON INFORMATION ON
RELATED MATERIALS. VIOLENT DECOMPOSITION MAY OCCUR
WHEN HEATED OR IN A FIRE BASED ON INFORMATION ON
RELATED MATERIALS. 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: 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. CLEAN SPILL AREA THOROUGHLY.

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.

MATERIAL NAME: LIBRIUM(R) CAPSULE MIX (10 MG)
MATERIAL CODE: 76201
MSDS NUMBER : M-012380.ASC

PAGE: 4
APPROVED: 02/28/96

SECTION 7. HANDLING AND STORAGE

HANDLING & STORAGE

PRECAUTIONS: DO NOT GENERATE DUST OR EXPOSE TO IGNITION SOURCES. GROUND AND BOND ALL TRANSFER EQUIPMENT. MILLING/MIXING/DRYING SHOULD BE PERFORMED IN DEVICES EQUIPPED WITH EXPLOSION RELIEF OR SUPPRESSION SYSTEMS OR UNDER INERT CONDITIONS. AVOID CONTACT WITH EYES, 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 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 COVERALS, 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

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. 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.

MATERIAL NAME: LIBRIUM(R) CAPSULE MIX (10 MG)
MATERIAL CODE: 76201
MSDS NUMBER .: M-012380.ASC

PAGE: 5
APPROVED: 02/28/96

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

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.

CHLORDIAZEPoxide HYDROCHLORIDE

ROCHE IOEL: 0.0500 MG/M₃ TIME WEIGHTED AVERAGE.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE: POWDER.
PURE/MIXTURE: MIXTURE.

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
DUST ACCUMULATION
AIRBORNE DUST
SOURCES OF IGNITION

POLYMERIZATION: NO

CONDITIONS OF

POLYMERIZATION: WILL NOT OCCUR.

SECTION 11. TOXICOLOGICAL INFORMATION

CHLORDIAZEPoxide HYDROCHLORIDE

ACUTE ORAL, SINGLE DOSE, RAT: 1030 MG/KG
SUMMARY: ACUTE ORAL LD₅₀ (RAT) IS 1030 MG/KG BODY WEIGHT AT 24 HOURS CLASSIFIES THIS MATERIAL AS MODERATELY TOXIC ORALLY UNDER THE STUDY CONDITIONS UTILIZED.

CARCINOGENICITY ORAL, 2 YEAR, RAT

SUMMARY: NO EVIDENCE OF CARCINOGENICITY WAS OBSERVED IN RATS WHEN ADMINISTERED AS A DIETARY ADMIX AT DOSES UP TO 100 MG/KG/DAY IN A TWO YEAR FEEDING STUDY, UNDER THE STUDY CONDITIONS UTILIZED.

MATERIAL NAME: LIBRIUM(R) CAPSULE MIX (10 MG)
MATERIAL CODE: 76201
MSDS NUMBER .: M-012380.ASC

PAGE: 6
APPROVED: 02/28/96

SECTION 11. TOXICOLOGICAL INFORMATION (CONTINUED. . .)

REPRODUCTIVE ORAL, RAT

SUMMARY: NO ADVERSE EFFECTS WERE OBSERVED IN RATS FED 10, 20, AND 80 MG/KG DAILY; HOWEVER, IN ANOTHER STUDY AT 100 MG/KG DAILY, THERE WAS SIGNIFICANT DECREASE IN THE FERTILIZATION RATE AND MARKED DECREASE IN THE VIABILITY AND BODY WEIGHT OF OFFSPRING WHICH MAY BE ATTRIBUTABLE TO SEDATIVE ACTIVITY (RESULTING IN LACK OF INTEREST IN MATING AND LESSENED MATERNAL NURSING AND CARE OF THE YOUNG).

TERATOGENICITY ORAL, RAT

SUMMARY: NO EVIDENCE OF TERATOGENICITY WAS OBSERVED IN RATS AT DOSES UP TO 100 MG/KG/DAY ADMINISTERED AS A DIETARY ADMIX DURING GESTATION, UNDER

THE STUDY CONDITIONS UTILIZED.

TERATOGENICITY ORAL, RABBIT

SUMMARY: NO EVIDENCE OF TERATOGENICITY WAS OBSERVED IN RABBITS AT DOSES UP TO 20 MG/KG/DAY ADMINISTERED ORALLY DURING GESTATION, UNDER THE STUDY CONDITIONS UTILIZED.

MUTAGENICITY

SUMMARY: NO EVIDENCE OF MUTAGENICITY WAS OBSERVED IN THE HOST-MEDIATED ASSAY, THE MOUSE MICRONUCLEUS ASSAY, AND IN THE AMES ASSAY WITH OR WITHOUT METABOLIC ACTIVATION, UNDER THE STUDY CONDITIONS UTILIZED.

SECTION 12. ECOLOGICAL INFORMATION

CHLORDIAZEPoxide HYDROCHLORIDE

NO OBSERVABLE EFFECT LEVEL, TROUT: 50.0 MG/L

SUMMARY: THIS MATERIAL IS CLASSIFIED AS MODERATELY TOXIC FOR FISH (RAINBOW TROUT); NEC = 50 MG/L, UNDER THE STUDY CONDITIONS UTILIZED.

AEROBIC BIODEGRADATION (H2O)

SUMMARY: THIS MATERIAL IS NOT BIODEGRADABLE (ZAHN-WELLENS-TEST) UNDER THS STUDY CONDITIONS UTILIZED.

SECTION 13. DISPOSAL CONSIDERATIONS

DISPOSAL

RECOMMENDATIONS: DISPOSE OF IN A MANNER APPROVED FOR U.S. DRUG ENFORCEMENT AGENCY SCHEDULE IV CONTROLLED SUBSTANCES. 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.

MATERIAL NAME: LIBRIUM(R) CAPSULE MIX (10 MG)
MATERIAL CODE: 76201
MSDS NUMBER : M-012380.ASC

PAGE: 7
APPROVED: 02/28/96

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: 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

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 CHLORDIAZEPoxide HYDROCHLORIDE WHICH IS KNOWN TO THE STATE TO CAUSE REPRODUCTIVE TOXICITY.

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 1
....FIRE 0
....REACTIVITY 0

APPROVAL INFORMATION

PREPARER: HESHAM M. SOLIMAN

APPROVER: CORPORATE ENVIRONMENTAL & SAFETY AFFAIRS

APPROVAL DATE: 02/28/96

REASON FOR ISSUE ...: NEW

THE INFORMATION PRESENTED ON THIS MSDS IS, TO THE BEST OF OUR KNOWLEDGE,
ACCURATE AND RELIABLE. IT IS PROVIDED IN GOOD FAITH WITHOUT WARRANTY OR
ACCEPTANCE OF ANY LIABILITY ON THE PART OF HOFFMANN-LAROCHE, INC. IT IS THE
RESPONSIBILITY OF THE USER TO EVALUATE THE RELEVANCE AND COMPLETENESS OF THIS
INFORMATION FOR THEIR APPLICATION AND TO DETERMINE THE SAFETY, SUITABILITY
AND STATUS UNDER APPLICABLE REGULATIONS RELATING TO THIS PRODUCT OR
BYPRODUCTS ARISING OUT OF THEIR PROCESS.