

BRISTOL-MEYERS SQUIBB PHARMACEUTICAL GROUP -- PROHANCE FOR
INJECTION -- 6505-01-371-4206

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Product Identification
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Product ID:PROHANCE FOR INJECTION
MSDS Date:01/20/1994
FSC:6505
NIIN:01-371-4206
Status Code:A
MSDS Number: CKLJG
=== Responsible Party ===
Company Name:BRISTOL-MEYERS SQUIBB PHARMACEUTICAL GROUP
Box:191
City:NEW BRUNSWICK
State:NJ
ZIP:08903
Country:US
Info Phone Num:908-519-3843
Emergency Phone Num:908-519-3843
Chemtrec Ind/Phone:(800)424-9300
CAGE:TO591
=== Contractor Identification ===
Company Name:BRISTOL-MEYERS SQUIBB PHARMACEUTICAL GROUP
Box:191
City:NEW BRUNSWICK
State:NJ
ZIP:08903
Country:US
Phone:908-519-3843
CAGE:TO591

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Composition/Information on Ingredients
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Ingred Name:GADOTERIDOL
CAS:120066-54-8
= Wt:24.

Ingred Name:WATER
CAS:7732-18-5
RTECS #:ZC0110000

Ingred Name:TROMETHAMINE
CAS:77-86-1
RTECS #:TY2900000
< Wt:1.

Ingred Name:CALTERIDOL CALCIUM
CAS:121915-83-1
< Wt:1.

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Hazards Identification
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LD50 LC50 Mixture:LD50 (RAT) > 5,880 MG/KG
Routes of Entry: Inhalation:NO Skin:NO Ingestion:NO

Reports of Carcinogenicity:NTP:NO IARC:NO OSHA:NO
Health Hazards Acute and Chronic:UNDER NORMAL CONDITIONS, THIS PRODUCT IS CONTAINED WITHIN VIALS AND SKIN/EYE CONTACT OR INHALATION WOULD NOT BE EXPECTED. PROHANCE FOR INJECTION CONTAINS GADOTERIDOL, A CONTRAST AGENT IN MAGNETIC RESONANCE IMAGING (MRI) INTENDED FOR INTRAVENOUS INJECTION, UNDER THE CARE OF A PHYSICIAN. WHEN ADMINISTERED PROPERLY, THIS PRODUCT CAN BE USED TO VISUALIZE SUBTLE BRAIN LESIONS. NAUSEA AND TASTE CHANGES WERE REPORTED IN 1.4% OF PATIENTS RECEIVING THIS INJECTION. ADVERSE CARDIOVASCULAR, DIGESTIVE, NERVOUS SYSTEM, RESPIRATORY, DERMAL AND AUDITORY EFFECTS WERE EXPERIENCED BY LESS THAN 1% OF PATIENTS.

Explanation of Carcinogenicity:NONE KNOWN.

Effects of Overexposure:NO INFORMATION.

Medical Cond Aggravated by Exposure:N/P.

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===== First Aid Measures =====

First Aid:INGEST: SEEK MEDICAL ATTENTION IMMEDIATELY. INDUCTION OF VOMITING SHOULD BE CONSIDERED FOR SIGNIFICANT INGESTION IF PERSON IS CONSCIOUS AND NOT EXPERIENCING CONVULSIONS. NEVER GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON. INHALE: REMOVE TO FRESH AIR. IF PERSON IS NOT BREATHING GIVE ARTIFICIAL RESPIRATION. IF BREATHING IS DIFFICULT ADMINISTER OXYGEN. SKIN: WASH WITH SOAP AND WATER. GET MEDICAL ATTENTION IF IRRITATION DEVELOPS AND PERSISTS. EYE: HOLD EYELIDS APART AND FLUSH WITH RUNNING WATER FOR AT LEAST 15 MINUTES. GET MEDICAL ATTENTION IMMEDIATELY.

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===== Fire Fighting Measures =====

Extinguishing Media:UNLIKELY TO BURN IN VIAL. IN CASE OF FIRE, FLOOD WITH WATER.

Fire Fighting Procedures:FIREFIGHTERS SHOULD WEAR SELF-CONTAINED BREATHING APPARATUS, FLAME AND CHEMICAL RESISTANT CLOTHING, BOOTS AND GLOVES. EVACUATE WITH WATER FROM A MAXIMUM DISTANCE.

Unusual Fire/Explosion Hazard:NONE KNOWN.

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===== Accidental Release Measures =====

Spill Release Procedures:ABSORB SPILL WITH INERT MATERIAL, E.G., SAND, VERMICULITE OR OTHER NON-COMBUSTIBLE ABSORBENT MATERIALS, AND PLACE INTO A CLOSED CONTAINER FOR RECLAMATION OR DISPOSAL. FLUSH RESIDUAL SPILL AREA WITH WATER TO PROCESS SEWER IF ALLOWABLE UNDER NATIONAL, STATE, OR LOCAL PERMITS OR REGULATIONS.

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===== Handling and Storage =====

Handling and Storage Precautions:DO NOT BREAK VIALS. AVOID SKIN AND EYE CONTACT. SHOULD BE STORED AT CONTROLLED ROOM TEMPERATURES (15 - 30 DEGREE C). DO NOT FREEZE.

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===== Exposure Controls/Personal Protection =====

Respiratory Protection:WHEN ENGINEERING CONTROLS ARE NOT SUFFICIENT TO CONTROL EXPOSURE, WEAR APPROVED RESPIRATORY PROTECTION APPROPRIATE FOR EXPOSURE POTENTIAL; SELF-CONTAINED BREATHING APPARATUS SHOULD BE AVAILABLE FOR EMERGENCY USE.

Ventilation:NONE BEYOND GOOD ROOM VENTILATION NORMALLY REQUIRED.

Protective Gloves:IMPERVIOUS GLOVES.

Eye Protection:SAFETY GLASSES.

Other Protective Equipment:WEAR PROTECTIVE OVERALLS WHENEVER THE POTENTIAL FOR SEVERE DUSTY CONDITIONS OR SPLASHING AND SPRAYING LIQUIDS EXISTS.

Work Hygienic Practices:WASH HANDS AFTER HANDLING COMPOUNDS AND BEFORE EATING, SMOKING, USING LAVATORY, AND AT THE END OF THE DAY.

Supplemental Safety and Health

===== Physical/Chemical Properties =====

HCC:N1

Boiling Pt:=100.C, 212.F

Melt/Freeze Pt:=0.C, 32.F

Spec Gravity:1.14

Evaporation Rate & Reference:SAME AS WATER

Solubility in Water:ABOUT 620 MG/ML

Appearance and Odor:CLEAR, COLORLESS TO SLIGHTLY YELLOW AQUEOUS LIQUID WHICH IS PACKAGED IN VIALS.

===== Stability and Reactivity Data =====

Stability Indicator/Materials to Avoid:YES ACIDS.

Stability Condition to Avoid:WHEN STORED AT CONTROLLED ROOM TEMPERATURES (15-30 DEGREE C) IN ORIGINAL CONTAINER, MATERIAL IS STABLE TO EXPIRATION DATE SHOWN ON PRODUCT LABEL.

Hazardous Decomposition Products:OXIDES OF CARBON, AND OXIDES OF NITROGEN.

===== Toxicological Information =====

Toxicological Information:IN LABORATORY ANIMALS, GADOTERIDOL WAS ESSENTIALLY NONTOXIC WHEN ADMINISTERED BY THE INTRAVENOUS ROUTE. AT DOSES, APPROXIMATELY 100 TIMES GREATER THAN THE CLINICAL DOSE, EXPERIMENTAL ANIMALS EXHIBITED ATAXIA, CONVULSIONS, COLLAPSE, IRREGULAR RESPIRATION. NO TREATMENT-RELATED PATHOLOGIC CHANGES WERE SEEN IN SURVIVING ANIMALS.

===== Ecological Information =====

Ecological:DAPHNIA ACUTE TOXICITY (EC50) > 920 MG/L. CHEMICAL FATE INFORMATION: HALF-LIFE 9HYDROLYSIS): < 10% HYDROLYSIS AFTER 5 DAYS AT 50 DEGREES C AT ALL PH LEVELS TESTED; CONSIDERED HYDROLYTICALLY STABLE. AE ROBIC BIODEGRADATION: HALF-LIFE DETERMINED TO BE GREATER THAN 28 DAYS.

===== Disposal Considerations =====

Waste Disposal Methods:DISPOSE OF IN ACCORDANCE WITH NATIONAL, STATE, LOCAL OR APPLICABLE COUNTRY REGULATIONS.

===== MSDS Transport Information =====

Transport Information:DOT: NOT REGULATED.

==== Regulatory Information =====

SARA Title III Information:NONE NOTES

Federal Regulatory Information:NONE NOTED

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