

GLAXO WELLCOME INC. -- PURINETHOL TABLETS -- 6505-00-226-3662

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Product Identification  
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Product ID: PURINETHOL TABLETS

MSDS Date: 06/23/1999

FSC: 6505

NIIN: 00-226-3662

Status Code: A

MSDS Number: CKKQH

=== Responsible Party ===

Company Name: GLAXO WELLCOME INC.

Address: FIVE MOORE DRIVE

Box: 13438

City: RESEARCH TRIANGLE PARK

State: NC

ZIP: 27709

Country: US

Info Phone Num: 919-248-2100

Emergency Pho

ne Num: 919-248-2700

CAGE: LO532

=== Contractor Identification ===

Company Name: GLAXO WELLCOME INC.

Address: 5 MOORE DR

Box: 13398

City: DURHAM

State: NC

ZIP: 27709

Country: US

Phone: 919-248-2100

CAGE: 34006

Company Name: GLAXO WELLCOME INC.

Address: FIVE MOORE DRIVE

Box: 13438

City: RESEARCH TRIANGLE PARK

State: NC

ZIP: 27709

Country: US

Phone: 919-248-2100

CAGE: LO532

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Composition/Information on Ingredients  
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Ingred Name: 6-MERCAPTOPYRIMIDINE MONOHYDRATE OR MERCAPTOPYRIMIDINE

CAS: 6112-76-1

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===== Hazards Identification =====  
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LD50 LC50 Mixture:LD50 (MOUSE) = 1250 MG/KG

Health Hazards Acute and Chronic:MERCAPTOPURINE IS A POWERFUL CYTOTOXIC AGENT. MAY BE HARMFUL IF SWALLOWED. MAY BE HARMFUL IF INHALED. MAY CAUSE SENSITIZATION OF SKIN. POSSIBLE RISK TO UNBORN CHILD. MUTAGEN AND PROBABLE HUMAN CARCINOGEN. POSSIBLE REPRODUCTIVE HAZARD. WHEN USED MEDICALLY, HAS BEEN ASSOCIATED WITH: BONE MARROW SUPPRESSION LEADING TO

ANEMIA, THROMBOCYTOPENIA, LEUKOPENIA, OR A COMBINATION OF THESE; LIVER TOXICITY (WITH JAUNDICE AND ELEVATED SERUM ENZYMES INDICATIVE OF LIVER DAMAGE), SKIN RASH, AND OTHER EVIDENCE OF HYPERSENSITIVITY, GASTROINTESTINAL ULCERATION AND OTHER ADVERSE GI EFFECTS (DIARRHEA).

Explanation of Carcinogenicity:MERCAPTOPURINE IS A PROBABLE HUMAN CARCINOGEN, BUT THE RISK IS UNKNOWN.

Effects of Overexposure:SIGNS AND SYMPTOMS OF OVERDOSAGE-IMMEDIATE: ANOREXIA, NAUSEA, VOMITING AND DIARRHEA. DELAYED: MYELOSUPPRESSION, LIVER DYSFUNCTION, GASTROENTERITIS. ADMINISTRATION OF PURINETHOL HAS BEEN ASSOCIATED WITH SKIN RASHES AND HYPERPIGMENTATION. OTHER SYMPTOMS: JAUNDICE, ELEVATED SERUM ENZYMES.

Medical Cond Aggravated by Exposure:RARE INDIVIDUALS WITH INHERITED DEFICIENCY OF THE ENZYME THIOPURINE METHYLTRANSFERASE (TPMT) MAY BE UNUSUALLY SENSITIVE TO THE MYELOSUPPRESSIVE EFFECTS OF MERCAPTOPURINE.

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===== First Aid Measures =====  
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First Aid:IN EYES: FLUSH IMMEDIATELY WITH LARGE QUANTITIES OF WATER FOR 15 MINUTES. OBTAIN MEDICAL ATTENTION. ON SKIN: REMOVE CONTAMINATED CLOTHES. FLUSH EXPOSED SKIN WITH WATER AND WASH THOROUGHLY WITH SOAP AND WATER. OBTAIN MEDICAL ATTENTION. INHALED: IF NOT BREATHING, GIVE ARTIFICIAL RESPIRATION OR CPR. IF BREATHING IS DIFFICULT, GIVE OXYGEN. REMOVE PERSON TO FRESH AIR. OBTAIN MEDICAL ATTENTION. INGESTED: IF CONSCIOUS, RINSE MOUTH WITH WATER. NEVER

GIVE ANYTHING BY MOUTH IF UNCONSCIOUS. OBTAIN MEDICAL ATTENTION.

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

Flash Point:NOT DETERMINED

Lower Limits:N/D

Upper Limits:N/D

Extinguishing Media:WATER SPRAY, MULTIPURPOSE DRY CHEMICAL.

Fire Fighting Procedures:WEAR FULL PROTECTIVE CLOTHING AND USE  
SELF--CONTAINED BREATHING APPARATUS (SCBA).

Unusual Fire/Explosion Hazard:AS FORMULATED, PURINETHOL TABLETS SHOULD  
BE DUST-FREE. HOWEVER, BREAKAGE OF TABLETS, ESPECIALLY  
IN BULK

OPERATIONS, COULD CONTRIBUTE TO DUST FORMATION. AS WITH ANY ORGANIC  
DUST, THERE IS POTENTIAL FOR EXPLOSION WHEN HIGH CONCENTRATIONS  
ARE SUSPENDED IN AIR. N/D= NOT DETERMINED.

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

Spill Release Procedures:PROTECTIVE EQUIPMENT MAY BE NECESSARY FOR  
SPILLS. SMALL QUANTITIES FROM NORMAL THERAPEUTIC USE: COLLECT  
SPILLAGE, MINIMIZING DUST AND TRANSFER TO CLOSED WASTE CONTAINER  
FOR DISPOSAL. LARGE BULK QUANTITIES:

COLLECT BY WET WIPING OR HEPA

VACUUMING AND PLACE IN A LABELED, SEALED CONTAINER FOR DISPOSAL.  
WASH SPILL AREA WITH SUITABLE CLEANING SOLVENT THEN WASH WITH  
WATER. CLEAN AREA WITH SOAP & WATER.

Neutralizing Agent:CLEANING SOLVENT: DILUTE ALKALINE PERMANGANATE  
SOLUTION.

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

Handling and Storage Precautions:AVOID MOISTURE BY ANY ROUTE. USE ONLY  
IN WELL-VENTILATED AREA WITH LIMITED ACCESS. PROPERLY IDENTIFY

(SIGNAGE & LABELS) POTENTIAL HAZARDS IN WORK AREAS. NO OPEN  
HANDLING OF POWDERS OR UNCOATED TABLETS UNLESS PRECAUTIONS HAVE  
BEEN TAKEN TO MINIMIZE SURFACE CONTAMINATION.

Other Precautions:AEROSOL-GENERATING PROCEDURES SHOULD BE CONDUCTED IN  
A LABORATORY FUME HOOD. DECONTAMINATE EQUIPMENT AND SURFACES  
THAT MAY HAVE COME IN CONTACT WITH COMPOUND. WASH HANDS AND OTHER  
EXPOSED SKIN THOROUGHLY BEFORE LEAVING WORK AREA. STORE AT 15-25C  
(59-77F) IN A DRY PLACE. KEEP IN

ORIGINAL CONTAINER TIG HTLY  
CLOSED.

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

Respiratory Protection:NOT REQUIRED UNDER NORMAL CONDITIONS OF THERAPEUTIC USE AND STORAGE. RESPIRATORY PROTECTIVE EQUIPMENT MAY BE NECESSARY TO PROVIDE ADDITIONAL PROTECTION FOR DUSTY PROCESSED AND IN THE ABSENCE OF SUFFICIENT ENGINEERING CONTROLS. USE NIOSH APPROVED RESPIRATORY PROTECTION TO CONTROL AIRBORNE LEVELS BELOW THE OEL.

Ventilation:NO SPECIAL VENTILATION REQUIREMENTS FOR NORMAL, THERAPEUTIC DOSAGE & ADMINISTRATION. FOR DUSTY PROCESSES: LOCAL EXHAUST VENTILATION.

Protective Gloves:USE IMPERMEABLE (E.G. LATEX) GLOVES TO PREVENT SKIN CONTACT.

Eye Protection:WORKERS SHOULD WEAR ADEQUATE EYE PROTECTION TO PREVENT EYE CONTACT.

Other Protective Equipment:ADEQUATE PROTECTIVE CLOTHING SHOULD BE WORN TO PREVENT OCCUPATIONAL SKIN CONTACT.

Work Hygienic Practices:SPECIAL CARE SHOULD BE TAKEN TO ENSURE THAT CONTAMINATED CLOTHING, EQUIPMENT, AND SURFACES ARE PROPERLY CLEANED AFTER USE. WASH HANDS AND OTHER AREAS OF SKIN CONTACT THOROUGHLY AFTER HANDLING.

Supplemental Safety and Health  
CONTAMINATED CLOTHING SHOULD BE DISPOSED OF OR CLEANED. POTENTIALLY CONTAMINATED CLOTHING SHOULD BE PACKAGED FOR LAUNDERING TO PREVENT EXPOSURE OF LAUNDRY PERSONNEL.

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

HCC:K2

Melt/Freeze Pt:=-300.C, 572.F

M.P/F.P Text:MERCAPTOPYRINE

Decomp Temp:=-300.C, 572.F

Solubility

in Water:0.26 MG/L: MERCAPTOPYRINE

Appearance and Odor:PURINETHOL TABLETS ARE PALE YELLOW TO BUFF SCORED TABLETS IMPRINTED WITH 04A

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

NOT DETERMINED FOR PURINETHOL TABLETS. NO KNOWN INCOMPATIBILITIES HAVE NOT BEEN IDENTIFIED FOR MERCAPTOPYRINE, THE ACTIVE INGREDIENT IN PURINETHOL TABLETS.

Stability Condition to Avoid:NOT DETERMINED.

Hazardous Decomposition Products:HAZARDOUS DECOMPOSITION PRODUCTS OF PURINET

HOL TABLETS HAVE NOT BEEN DETERMINED. THERMAL DECOMPOSITION PRODUCTS OF MERCAPTOPYRINE: OXIDES OF NITROGEN AND SULFUR.

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

Toxicological Information: PHARMACOLOGICAL ACTIVITY: PURINETHOL IS A POTENT CYTOTOXIC AGENT AND IS INDICATED FOR REMISSION INDUCTION AND MAINTENANCE THERAPY OF ACUTE LYMPHATIC LEUKEMIA. OCCUPATIONAL EXPOSURE LIMITS (MERCAPTOPYRINE): GLAXO-WELLCOME TWA: 10 MCG/M<sup>3</sup>. ACUTE TOXICITY: THE APPROXIMATE LETHAL DOSE OF MERCAPTOPYRINE FOLLOWING SINGLE ORAL ADMINISTRATION WAS: LD<sub>50</sub> (MOUSE) = 1250 MG/KG. REPEAT DOSE TOXICITY: SAME ADVERSE EFFECTS AS WHEN USED MEDICALLY: MYELOSUPPRESSION, HEPATOTOXICITY, GASTROINTESTINAL TOXICITY. ADVERSE CHANGES TO IMMUNE SYSTEM MAY ALSO ACCOMPANY EXPOSURE TO THIS SUBSTANCE.

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

Ecological: ENVIRONMENTAL FATE: MERCAPTOPYRINE MONOHYDRATE COMPARTMENTALIZES IN THE AQUATIC ENVIRONMENT. ENVIRONMENTAL EFFECTS: MERCAPTOPYRINE MONOHYDRATE IS UNLIKELY TO BIOACCUMULATE AND BIODEGRADE, IT SHOWS TOXICITY TO AQUATIC REPTILES AT 72 MG/L. ENVIRONMENTAL TEST RESULTS: WATER SOLUBILITY: 0.105 MG/ML (20°C); N-OCTANOL/WATER PARTITION COEFFICIENT: LOG P 1000 MG/L; ACUTE TOXICITY TO DAPHNIA: EC<sub>50</sub> = 72 MG/L; NOEC = 32 MG/L.

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

Waste Disposal Methods: ROUTINE: UNUSED PRODUCT SHOULD BE DISPOSED OF AT AN APPROVED FACILITY IN ACCORDANCE WITH FEDERAL, STATE AND LOCAL REGULATIONS. ACCIDENTAL RELEASE: CLEAN UP SPILLS IMMEDIATELY AS PREVIOUSLY NOTED, OBSERVING PRECAUTIONS FOR PERSONAL PROTECTION. REMOVE OR DECONTAMINATE ALL RESIDUES IAW FEDERAL, STATE AND LOCAL REGULATIONS.

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

Transport Information: US DOT PROPER SHIPPING NAME: NOT REGULATED FOR TRANSPORTATION. IATA/ICAO PROPER SHIPPING NAME: NOT REGULATED

FOR  
TRANSPORTATION. IMDG PROPER SHIPPING NAME: NOT REGULATED FOR  
TRANSPORTATION. RQ = NONE. MARINE POLLUTANT: NO.

===== Regulatory Information =====

SARA Title III Information:NO DATA PROVIDED BY RESPONSIBLE PARTY.  
Federal Regulatory Information:NO DATA PROVIDED BY RESPONSIBLE PARTY.  
State Regulatory Information:NO DATA PROVIDED BY RESPONSIBLE PARTY.

===== Other Information =====

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