

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

===== Product Identification =====

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 Phone 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

===== Composition/Information on Ingredients =====

Ingred Name: 6-MERCAPTOPURINE MONOHYDRATE OR MERCAPTOPURINE

CAS: 6112-76-1

RTECS #: UP0400000

===== 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, GAST

ROENTERITIS. ADMINISTRATION OF PURINETHOL

HAS BEEN ASSOCIATED WITH SKIN RASHES AND HYPERPIGMENTATION. OTHER SYMPTOMS: JAUNDICE, ELEVATED SERUM ENZYMES.

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

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

First Aid:IN EYES: FLUSH IMMEDIATELY WITH LARGE Q

UANTITIES 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.

N.

===== 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 W

ITH 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 QUANTI TIES: COLLECT BY WET WIPING OR HEPA VACUUMING AND PALCE

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 O PEN

HANDLING OF POWDERS OR UNCOATED TABLETS UNLESS PRECAUTIONS HAVE BEEN ATKEN TO MINIMIZE SURFACE CONTAMINATION.

Other Precautions:AEROSOL-GENERATING PROCEDURES SHOULD BE CONDUCTED IN A LABORATORY FUME HOOD. DECONTAMINATE EQUIPMENT AND SURFACES THATMAY HAVE COME IN CONTACT WITH COMPOUND. WASH HANDS AND OTHER EXPOSED SKIN THOROUGH LY 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 SUFFIC ENT 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:MERCAPTOPURINE
Decomp Temp:=300.C, 572.F
Solubility in Water:0.26 MG/L: MERCAPTOPURINE
Appearance and Odor:PURI
NETHOL 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 MERCAPTOPURINE, THE ACTIVE INGREDIENT IN PURINETHOL TABLETS.
Stability Condition to Avoid:NOT DETERMINED.
Hazardous Decomposition Products:HAZARDOUS DECOMPOSITION PRODUCTS OF PURINETHOL TABLETS HAVE NOT BEEN DETERMINED. THERMAL DECOMPOSITION PRODUCTS OF MERCAPTOPURINE: OXIDES OF NITROGEN AND SULFUR.

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

Toxicological Information:PHARMOCOLOGICAL ACTIVITY: PURINETHOL IS A POTENT CYTOTOXIC AGENT AND IS INDICATED FOR REMISSION INDUCTION AND MAINTENANCE THERAPY OF ACUTE LYMPHATIC LEUKEMIA. OCCUPATIONAL EXPOSURE LIMITS (MERCAPTOPURINE): GLAXO-WELLCOME TWA: 10 MCG/M3. ACUTE TOXICITY: THE APPROXIMATE LETAL DOSE OF MERCAPTOPURINE FOLLOWING SINGLE ORAL ADMIN

ISTRATION WAS: LD50 (MOUSE) = 1250
MG/KG. REPEAT DOSE TOXICITY: SAME ADVERS E EFFECTS AS WHEN USED
MEDICALLY: MYELOSUPPRESSION, HEPATOTOXICITY, GASTROINTESTINAL
TOXICITY.ADVERSE CHANGES TO IMMUNE SYSTEM MAY ALSO ACCOMPANY
EXPOSUERE TO THIS SUBSTANCE.

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

Ecological:ENVIORONMENTAL FATE: MERCAPTOPURINE MONOHYDRATE
COMPARTMENTALIZES IN THE AQUATIC ENVIRONMENT. ENVIRONMENTAL
EFFECTS: MERCAPTOPURINE MONOHYDRATE
IS UNLIKELY TO BIOACCUMULATE
AND BIODEGRADE, IT SHOWS TO XICITY TO AQUATIC REPTORS AT 72 MG/L.
ENVIRONMENTAL TEST RESULTS: WATER SOLUBILITY: 0.105 MG/ML (205C);
N-OCTANOL/WATER PARTITION COEFFICIENT: LOG P 1000 MG/L; ACUTE TOXICITY TO DAPHNIA:
EC50 = 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 LO
CAL
REGULATIONS. ACCIDENTAL RELEASE: CLEAN UP SPILLS IMMEDIATELY AS
PREVIOUSLY NOTED, OBSE RVING PRECAUTIONS FOR PERSONAL PROTECTION.
REMOVE OR DECONTAMINATE ALL RESIDUES IAW FEDERAL, STATE A ND LOCAL
REGULATIONS.

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

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