SAFETY DATA SHEET

GlaxoSmithKline

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material **MALOPRIM TABLETS**

Synonyms MALOPRIM TABLETS 12.5 MG * PYRIMETHAMINE 12.5 MG AND DAPSONE 100 MG TABLETS * PYRIMETHAMINE AND DAPSONE, FORMULATED PRODUCT

Company Name

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2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
DAPSONE	80-08-0	34.5
PYRIMETHAMINE	58-14-0	4.3
NON-HAZARDOUS INGREDIENTS	Unassigned	61.2

3. HAZARDS IDENTIFICATION

Fire and Explosion Expected to be non-combustible.

Health	Caution - Pharmaceutical agent. May produce mutagenic effects in human cells. May produce adverse effects on human fertility. May produce adverse effects on the development of human offspring. Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); irregular heartbeat; anorexia; vomiting; temporary decrease in platelet count; temporary decrease in white blood cell count; anaemia; nervousness; muscle weakness; convulsions. Exposure might occur via ingestion; skin; eyes Health effects information is based on hazards of components. Handling this product in its final form presents minimal risk from occupational exposure.
Environment	Dangerous for the environment. Harmful to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

4. FIRST-AID MEASURES

Ingestion	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin Contact	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye Contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.
Medical Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.
Health Surveillance Procedures	Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.
Extinguishing Media	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	Water can be used for clean-up and decontamination operations. No specific decontamination or detoxification procedures have been identified for this product.

7. HANDLING AND STORAGE

HANDLING

General Requirements	Avoid breaking or crushing tablets.
STORAGE	No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT	DAPSONE	
GSK Occupational Hazard Category	2	
INGREDIENT	PYRIMETHAMINE	
GSK Occupational Hazard Category	4	
GSK Occupational Exposure Limit	7 mcg/m3 (8 HR TWA)	REPRODUCTIVE HAZARD

ENGINEERING CONTROLS

Exposure Controls	An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them.
Administrative	New or expectant mothers might be at greater risk from overexposure. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices.

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection	Wear approved safety glasses with side shields if eye contact is possible.
Respirators	If respiratory protective equipment (RPE) is used, the type of RPE will depend upon air concentrations present, required protection factor as well as hazards, physical properties and warning properties of substances present. Follow local regulations for respirator use in the workplace.
Other Equipment or Procedures	Wash hands and arms thoroughly after handling. An eye wash station should be available.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Colour	White.
Physical Form	Tablet.

10. STABILITY AND REACTIVITY

Stability	This product is expected to be stable.
Conditions to Avoid	None for normal handling of this product.

11. TOXICOLOGICAL INFORMATION

*** Oral Toxicity**	Adverse effects might occur following ingestion.
*** Skin Effects**	Minor irritation might occur following direct contact.
*** Eye Effects**	Minor irritation might occur following direct contact with eyes.
*** Target Organ Effects**	Adverse effects might occur in the following organ(s) following overexposure: kidney; bone marrow and formation of blood cells.
*** Sensitisation**	Potential for inducing allergic reactions via the dermal or respiratory route is not known.
*** Genetic Toxicity**	Possible human mutagen.
*** Carcinogenicity**	No components are listed as carcinogens by GSK, IARC, NTP or US OSHA. Not expected to produce cancer in humans under occupational exposure conditions.
*** Reproductive Effects**	Contains components which have been classified as: Possible risk of toxicity in developing human offspring. Possible risk of affecting the quantity or the quality of breast milk in humans.
*** Pharmacological Effects**	This product contains active ingredient(s) with the following activity: an inhibitor of folic acid metabolism.
*** Other Adverse Effects**	None known for occupational exposure.

12. ECOLOGICAL INFORMATION

*** Summary**

This material contains two or more active pharmaceutical ingredients that have been tested, one of which may be harmful if released directly to the environment. Specific information on that active pharmaceutical ingredient is provided below.

Appropriate precautions should be taken to limit release of this material to the environment. Local regulations and procedures should be consulted prior to environmental release.

ECOTOXICITY

Aquatic

*** Activated Sludge Respiration**	This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.	
	IC50:	> 3200 mg/l, 3 Hours, Activated sludge, Nominal
	NOEC:	10 , 3 Hours
*** Algal**	This material contains an active pharmaceutical ingredient that is harmful to algae.	
	IC50:	20 mg/l, 48 Hours, Chlorella pyrenoidosa, green algae
*** Daphnid**	This material contains an active pharmaceutical ingredient that is toxic to daphids.	
	EC50:	4.8 mg/l, 48 Hours, Daphnia magna, Static test

*** Fish** This material contains an active pharmaceutical ingredient that is toxic to fish.

Juvenile Oncorhyncus mykiss, rainbow trout
EC50: 5.9 mg/l, 48 Hours, Static test

MOBILITY

*** Solubility** This material contains an active pharmaceutical ingredient that for environmental fate predictions has limited solubility in water.

*** Volatility** This material contains an active pharmaceutical ingredient that will not readily enter into air from water.

Henry's Law Constant 1.08E-10 atm m^3/mol, Estimated at 25 C

*** Partitioning** This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION

*** Hydrolysis** This material contains an active pharmaceutical ingredient that has been shown to be chemically stable in water. Hydrolysis is unlikely to be a significant depletion mechanism.

Half-Life, Neutral: 6 Months, Measured, Deionized Water

*** Biodegradation** This material contains an active pharmaceutical ingredient that is not readily biodegradable (as defined by 1993 OECD Testing Guidelines). It may persist in the environment.

Aerobic - Inherent
Percent Degradation: 2 %, 28 days, Modified MITI (II) Test., Activated sludge

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

Regulatory Requirements Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling

Transport Information Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

*** EU Classification and Labelling**

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)

Classification This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

Date Approved/Revised 21-Jan-2005 **SDS Version Number** 4

SDS Sections Updated

Sections	Subsections
COMPOSITION / INFORMATION ON INGREDIENTS	
ECOLOGICAL INFORMATION	Activated Sludge Respiration
	Adsorption
	Algal
	Algal Degradation
	Bioaccumulation
	Biodegradation
	Daphnid
	Distribution
	Earthworm
	Ecotoxicity
	Fish
	Hydrolysis
	Microbial Growth Inhibition
	Microtox
	Mobility
	Other Adverse Effects
	Other Species - Aquatic
	Other Species - Terrestrial
	Partitioning
	Persistence/Degradation
	Photolysis
	Solubility
	Summary
	Volatility
REGULATORY INFORMATION	European Union Classification and Labelling Requirements
TOXICOLOGY INFORMATION	Carcinogenicity
	Eye Effects
	Genetic Toxicity
	Inhalation Toxicity
	Oral Toxicity
	Other Adverse Effects
	Pharmacological Effects
	Reproductive Effects
	Sensitisation
	Skin Toxicity
	Target Organ Effects

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.