

SAFETY DATA SHEET



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

Material	DARAPRIM TABLETS
Synonym(s)	DARAPRIM TABLETS 25 MG * DARAPRIM COMPRIMES * DARAPRIM COMPRIMIDOS * DARAPRIM TABLETAS * DARAPRIM TABLETKI * DARAPRIM TABLETTEN * NDC NO 0173-0201-55 * PYRIMETHAMINE, FORMULATED PRODUCT
Company Name	<p>GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK</p> <p>UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333 Medical Emergency +1-612-221-3999, Ext 221 Information and Advice: US number, available 24 hours Multi-language response</p> <p>GlaxoSmithKline, Corporate Environment, Health & Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US</p> <p>US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response</p>

* 2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
NON-HAZARDOUS INGREDIENTS	Unassigned	82.5	
PYRIMETHAMINE	58-14-0	17.5	

3. HAZARDS IDENTIFICATION

Fire and Explosion	Expected to be non-combustible.
Health	<p>Caution - Pharmaceutical agent.</p> <p>Exposure might occur via skin; eyes; ingestion.</p> <p>May produce mutagenic effects in human cells.</p> <p>May produce adverse effects on the development of human offspring.</p> <p>May impair the quantity or quality of human milk production.</p> <p>Health effects information is based on hazards of components.</p>
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.
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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	Medical treatment in cases of overexposure should be treated as an overdose of an inhibitor of folic acid metabolism. 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	None for occupational exposure.
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	Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	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	PYRIMETHAMINE	
GSK Occupational Hazard Category	4	
GSK Occupational Exposure Limit	7 mcg/m3 (8 HR TWA)	REPRODUCTIVE HAZARD
ENGINEERING CONTROLS		
Containment	Open handling may result in overexposure. Consider use of enclosures.	

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Administrative Entry to the working area should be controlled. Restrict access to authorised personnel. 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.

Other Equipment or Procedures Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

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. TOXICOLOGY INFORMATION

Pharmacological Effects This product contains active ingredient(s) with the following activity: an inhibitor of folic acid metabolism.

Target Organ Effects Adverse effects might occur in the following organ(s) following overexposure: kidney; bone marrow and formation of blood cells.

Routes of Exposure

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.

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.

Other Adverse Effects None known for occupational exposure.

12. ECOLOGICAL INFORMATION

Summary This material contains an active pharmaceutical ingredient that has been tested and which may be harmful if released directly to the environment. This material contains an active pharmaceutical ingredient that may persist in the environment. Consult the MSDS of the active ingredient for specific information about potential environmental effects. 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.

Specific information on the active pharmaceutical ingredient is provided below.

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.

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	IC50:	20 mg/l, 48 Hours, Chlorella pyrenoidosa, green algae
Daphnid	This material contains an active pharmaceutical ingredient that is toxic to daphnids.	
	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. The recommended method of disposal is incineration.
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.
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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.
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Other US Regulations

TSCA Status

Exempt

16. OTHER INFORMATION

References

GSK Hazard Determination

SDS Version Number

7

SDS Sections Updated**Sections****Subsections**

COMPOSITION / INFORMATION ON INGREDIENTS

IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF
COMPANY

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.