SAFETY DATA SHEET

GlaxoSmithKline

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

Material **HALFAN TABLETS**

Synonyms HALFAN 250 MG TABLETS * HALOFANTRINE HYDROCHLORIDE, FORMULATED PRODUCT

Company Name

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US General Information:	+1-888-825-5249
Transport Emergency (non EU)	+1-703-527-3887 US number, available 24 hours Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
HALOFANTRINE HYDROCHLORIDE	36167-63-2	67
NON-HAZARDOUS INGREDIENTS	Unassigned	33

3. HAZARDS IDENTIFICATION

Fire and Explosion This product is expected to be non-combustible.

Health Exposure might occur via ingestion; skin; eyes.
Possible effects of overexposure in the workplace include: abdominal pain; diarrhoea; vomiting; rash; headache.
Health effects information is based on hazards of components.

Environment Dangerous for the environment. Toxic 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 local poison control information centre. Medical treatment in cases of overexposure should be treated as an overdose of an anti-parasitic.
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 or foam extinguishers are recommended. Carbon dioxide or dry powder 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	HALOFANTRINE HYDROCHLORIDE
GSK Occupational Hazard Category	1
GSK Occupational Exposure Limit	2000 MCG/M3 (8 HR TWA)

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection	Wear approved safety glasses with side shields if eye contact is possible.
Other Equipment or Procedures	None required for normal handling. Wear appropriate clothing to avoid skin contact.

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. TOXICOLOGICAL INFORMATION

Oral Toxicity	Not expected to be toxic following ingestion.
Skin Effects	Irritation is not expected following direct contact.
Eye Effects	Minor irritation might occur following direct contact with eyes.
Target Organ Effects	No specific target organ effects have been identified.
Sensitisation	Sensitisation (allergic skin reaction) is not expected.
Genetic Toxicity	Not expected to be genotoxic under occupational exposure conditions.
Carcinogenicity	Not expected to produce cancer in humans under occupational exposure conditions. No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
Reproductive Effects	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
Pharmacological Effects	This product is intended for the treatment of malaria. Adverse effects of overexposure might include: abdominal discomfort; diarrhoea; vomiting; rash; headache.
Other Adverse Effects	None known for this material in humans.

12. ECOLOGICAL INFORMATION

Summary	No information is available about the potential of this product to produce adverse environmental effects. This product contains an active ingredient that has been tested and which may be harmful if released directly to the environment. 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

Microtox	Microtox is a general toxicity test which utilizes a sensitive marine photo bacteria as the test species. This material contains an active pharmaceutical ingredient that is toxic to these microorganisms.
Daphnid	This mixture contains an active pharmaceutical ingredient that is toxic to daphnids.

MOBILITY

Solubility	This mixture contains an active pharmaceutical ingredient that for environmental fate predictions has very low solubility in water.
Adsorption	This mixture contains an active pharmaceutical ingredient that is likely to adsorb to sludges and other biomass. It may persist in sludges or other biomass if released directly to the environment.
Partitioning	This mixture contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient may have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION

Photolysis	This mixture contains an active pharmaceutical ingredient that is unlikely to undergo photodegradation.

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

None.

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 20-Aug-2003 **SDS Version Number** 11

SDS Sections Updated

Sections	Subsections
EXPOSURE CONTROLS / PERSONAL PROTECTION	Administrative
	Containment
	Exposure Controls
	Eye Protection
	Gloves
	Occupational Hygiene Air Monitoring Methods
	Occupational Hygiene Surface Monitoring Metho
	Other Equipment or Procedures
	Other Exposure Limits
	Other Information
	Other Protective Equipment
	Respirators
	Surface Exposure Target
	Ventilation
HAZARDS IDENTIFICATION	Conditions Aggravated by Exposure
	Environment
	Eye Contact
	Health
	Ingestion
	Inhalation
	Overview
	Skin Contact
	Summary
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.