SMKLP# HC# 42

SAFETY DATA SHEET

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GlaxoSmithKline

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

Material **MALARONE TABLETS**

Synonyms MALARONE TABLETS 250/100MG * MALARONE COMPRIMES * MALARONE COMPRIMES PELLICULES * MALARONE COMPRIMIDOS * MALARONE FILMTABLETTEN * MALARONE TABLETTEN * MALARONE TABLETTER * NDC NO 0173-0675-01 * NDC NO 0173-0675-00 * NDC NO 0173-0675-02 * NDC NO 0173-0676-01 * NDC NO 0173-0676-00 * NDC NO 0173-0676-02 * ATOVAQUONE AND PROGUANIL HYDROCHLORIDE, FORMULATED PRODUCTS

Company Name GlaxoSmithKline, Corporate Environment, Health & Safety
980 Great West Road
Brentford, Middlesex TW8 9GS UK

UK General Information:	+44-20-8047-5000
Transport Emergency (EU)	+44-1865-407333
Medical Emergency Information and Advice:	+1-612-221-3999, Ext 221 US number, available 24 hours Multi-language response

GlaxoSmithKline, Corporate Environment, Health & Safety
2200 Renaissance Blvd, Suite 105
King of Prussia, PA 19406 US

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
ATOVAQUONE	95233-18-4	40
PROGUANIL HYDROCHLORIDE	637-32-1	16
NON-HAZARDOUS INGREDIENTS	Unassigned	44

3. HAZARDS IDENTIFICATION

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

Health Handling this product in its final form presents minimal risk from occupational exposure. Health effects information is based on hazards of components. Caution - Pharmaceutical agent.

Environment Dangerous for the environment. Very 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 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.

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 Detergent solutions can be used for clean-up and decontamination operations.

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	ATOVAQUONE
GSK Occupational Hazard Category	2
GSK Occupational Exposure Limit	200 mcg/m3 (8 HR TWA)
INGREDIENT	PROGUANIL HYDROCHLORIDE
GSK Occupational Hazard Category	2
GSK Occupational Exposure Limit	500 mcg/m3 (15 MIN STEL)
Other Equipment or Procedures	None required for normal handling. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Colour	Pink.
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	Irritation is not expected following direct contact.
Eye Effects	Irritation is not expected following direct contact with eyes.
Target Organ Effects	Adverse effects might occur in the following organ(s) following overexposure: kidney; lymph nodes; thymus; gastro-intestinal tract; bone marrow and formation of blood cells.
Sensitisation	Sensitisation (allergic skin reaction) is not expected.
Genetic Toxicity	Not expected to be genotoxic under occupational exposure conditions.
Carcinogenicity	Atovaquone, the active substance in this product, produced carcinogenic effects in a lifetime study in mice. 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 contains active ingredient(s) with the following activity: an inhibitor of electron transport; an inhibitor of folic acid metabolism. It is an agent intended for the treatment of malaria. Adverse effects of overexposure might include: headache; gastrointestinal distress; weakness; dizziness; nosebleed; blocked nose; sore throat; sensation of bitter taste.
Other Adverse Effects	None known for this material in humans.

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. 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

Microbial Growth Inhibition

No toxicity to these microorganisms was observed for the active pharmaceutical ingredient of this mixture, but the upper range of the test was limited by the low water solubility of the compound.

Minimum Inhibition Concentration:	> 11 mcg/l, , Aspergillus flavus
	> 11 mcg/l, , Azotobacter chroococcum
	> 11 mcg/l, , Chaetomium globosum
	> 11 mcg/l, , Nostoc sp.

Daphnid

This mixture contains an active pharmaceutical ingredient that is very toxic to daphnids.

EC50:	0.0035 mg/l, 48 Hours, Daphnia magna, Static test
NOEL:	0.0018 mg/l, 48 Hours, Daphnia magna, Static test

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 soil or sediment. It may persist in soil or sediment if released directly to the environment.

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.

Soil Sediment Sorption (log Koc):	4.18 to 4.58, Measured
Sludge Biomass Distribution Coefficient (log Kd):	3.91 to 4.31 Calculated

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 material contains and active pharmaceutical ingredient that has been shown to be chemically unstable in water when exposed to light. Aqueous photolysis may be a significant depletion mechanism.

Half-Life, Aqueous: 2.63 Hours, Measured

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.

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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 This product is not regulated according to IATA, IMDG, US DOT or ADR/RID requirements.

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 23-Aug-2003 **SDS Version Number** 4

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.