

SAFETY DATA SHEET



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

Material	MALARONE TABLETS
Synonym(s)	MALARONE TABLETS 250 MG/100 MG * MALANIL TABLETS * NDC NO 0173-0675-01 * NDC NO 0173-0675-02 * ATOVAQUONE AND PROGUANIL HYDROCHLORIDE, 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.
ATOVAQUONE	95233-18-4	40	
NON-HAZARDOUS INGREDIENTS	Unassigned	44	
PROGUANIL HYDROCHLORIDE	637-32-1	16	

3. HAZARDS IDENTIFICATION

Fire and Explosion	Expected to be non-combustible.
Health	<p>Caution - Pharmaceutical agent. Handling this product in its final form presents minimal risk from occupational exposure.</p> <p>Health effects information is based on hazards of components.</p> <p>Possible effects of overexposure in the workplace include: headache; nausea; insomnia; yellow discolouration of the skin; diarrhoea; rash.</p>
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. TOXICOLOGY INFORMATION

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.

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.

Routes of Exposure

Oral Toxicity Adverse effects might occur following ingestion. Assessment based upon effects of individual components.

Skin Effects Irritation is not expected following direct contact. Assessment based upon effects of individual components.

Eye Effects Irritation is not expected following direct contact with eyes. Assessment based upon effects of individual components.

Sensitisation Sensitisation (allergic skin reaction) is not expected. Assessment based upon effects of individual components.

Genetic Toxicity Not expected to be genotoxic under occupational exposure conditions. Assessment based upon effects of individual components.

Carcinogenicity Not expected to produce cancer in humans under occupational exposure conditions. Assessment based upon effects of individual components.

Reproductive Effects Not expected to produce adverse effects on fertility or development under occupational exposure conditions. Assessment based upon effects of individual components.

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****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.
> 11 mcg/l, , Pseudomonas acidovorans

Daphnid

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

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

NOEC: 0.0018 mg/l, 48 Hours, Daphnia magna, Static test

Terrestrial**Earthworm**

This mixture contains an active pharmaceutical ingredient that is not toxic to earthworms.

EC50: > 1000 mg/kg, 14 Days, Eisenia foetida, manure worm, Nominal

NOEC: 1000 mg/kg, 14 Days, Eisenia foetida, manure worm, Nominal

MOBILITY**Solubility**

This material contains an active pharmaceutical ingredient that for environmental fate predictions has very low solubility in water.

Adsorption

This material contains an active pharmaceutical ingredient that is likely to adsorb to soil or sediment. This material contains an active pharmaceutical ingredient that is likely to adsorb to sludges and other biomass.

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 material 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 an 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

Aerobic - Soil

Percent Degradation: 75 %, 1 Day, , Soil

Bioaccumulation

This material contains an active pharmaceutical ingredient that will have a tendency to bioaccumulate in the food chain.

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.
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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
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Australian Classification according to Hazardous Substance and Dangerous Goods Regulatory Framework	This product is classified as hazardous according to the NOHSC Approved Criteria for Classifying Hazardous Substances.
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16. OTHER INFORMATION

References	GSK Hazard Determination
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SDS Version Number	9
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SDS Sections Updated

Sections	Subsections
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.