

SAFETY DATA SHEET



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

Material	MEPRON SUSPENSION
Synonym(s)	MEPRON SUSPENSION 750 MG/5 ML * WELLVONE SUSPENSION 750 MG/5 ML * WELLVONE SUSPENSIO 150 MG/ ML * NDC NO 0173-0547-00 * NDC NO 0173-0665-18 * ATOVAQUONE, 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	15	
NON-HAZARDOUS INGREDIENTS	Unassigned	85	

3. HAZARDS IDENTIFICATION

Fire and Explosion	Expected to be non-combustible.
Health	<p>Handling this product in its final form presents minimal risk from occupational exposure. 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. 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.

Material MEPRON SUSPENSION

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	No special requirements needed.
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 leakage of this material occurs, contain and collect 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	Spread an inert absorbent on the spill and place 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	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
-----------------------------	--

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/m ³ (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. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form Suspension.

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 It is an agent intended for the treatment of parasitic infection. Adverse effects of overexposure might include: headache; rash; diarrhoea; nausea; insomnia; vomiting.

Target Organ Effects No specific target organ effects have been identified.

Routes of Exposure

Oral Toxicity Not expected to be toxic following ingestion.

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.

Reproductive Effects Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

Other Adverse Effects Overexposure in the workplace might have the following effects: yellow discolouration of the skin. The following adverse effects have been noted with therapeutic use of this material: symptoms of hypersensitivity (such as skin rash, hives, itching, and/or difficulty breathing).

12. ECOLOGICAL INFORMATION

Summary This material contains an active pharmaceutical ingredient that has been tested, and which may be very toxic to aquatic organisms 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.

Specific information on the active pharmaceutical ingredient is provided below.

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

Material MEPRON SUSPENSION

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.

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.

Material MEPRON SUSPENSION

US OSHA Standard (29 CFR Part 1910.1200)**Classification** This product is classified as hazardous according to the OSHA Hazard Communication Standard.**Other US Regulations****TSCA Status** Exempt

16. OTHER INFORMATION

References GSK Hazard Determination**SDS Version Number** 10**SDS Sections Updated****Sections****Subsections**

COMPOSITION / INFORMATION ON INGREDIENTS

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.