



SAFETY DATA SHEET

1. Identification

Product identifier MEPRON SUSPENSION

Other means of identification

Synonyms

MEPRON SUSPENSION 750 MG/5 ML * WELLVONE SUSPENSION 750 MG/5 ML * WELLVONE SUSPENSIO 150 MG/ ML * SAMTIREL * ATOVAQUONE SUSPENSION 750MG/5ML * ATOVAQUONE, FORMULATED PRODUCT

Recommended use Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
ATOVAQUONE	566C80 * GR151218X * TRANS-2(4-(4-CHLOROPHENYL)CYCLOH EXYL)-3-HYDROXY-1,4-N APHTHOQUINONE * 1672 (GW ACN)	95233-18-4	15
BENZYL ALCOHOL	BENZENEMETHANOL * BENZENECARBINOL * (HYDROXYMETHYL)BENZENE * ALPHA-HYDROXYTOLUENE * PHENYLCARBINOL * PHENYLMETHANOL * PHENYLMETHYL ALCOHOL * ALPHA-TOLUENOL * C7H8O * OHS02800 * RTECS DN3150000	100-51-6	1
Other components below reportable levels			84.0

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical advice/attention if you feel unwell.
Most important symptoms/effects, acute and delayed	The following adverse effects have been noted with therapeutic use of this material: headache; nausea; insomnia; yellow discolouration of the skin; diarrhoea; rash; vomiting.
Indication of immediate medical attention and special treatment needed	Treat symptomatically.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire-fighting equipment/instructions	Move containers from fire area if you can do so without risk.
General fire hazards	Expected to be non-combustible.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills in original containers for re-use. For waste disposal, see section 13 of the SDS.
Environmental precautions	Prevent further leakage or spillage if safe to do so.

7. Handling and storage

Precautions for safe handling	Use care in handling/storage.
Conditions for safe storage, including any incompatibilities	Store in accordance with local/regional/national/international regulation. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components

ATOVAQUONE (CAS
95233-18-4)

Type

8 HR TWA

Value

200 mcg/m³

OHC

2

US. AIHA Workplace Environmental Exposure Level (WEEL) Guides

Components

BENZYL ALCOHOL (CAS
100-51-6)

Type

TWA

Value

44.2 mg/m³

10 ppm

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection	If contact is likely, safety glasses with side shields are recommended.
Hand protection	For prolonged or repeated skin contact use suitable protective gloves. The selection of gloves for a specific activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Care must be exercised if insufficient data are available and further guidance should be sought from your local EHS department. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided. Glove selection must take into account any solvents and other hazards present.
Skin protection	
Other	Wear suitable protective clothing.
Respiratory protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state	Liquid.
Form	Suspension.
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	Not available.
Chemical stability	Material is stable under normal conditions.

Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	None known.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Based on available data, the classification criteria are not met.
Inhalation	Due to lack of data the classification is not possible.
Skin contact	Based on available data, the classification criteria are not met.
Eye contact	Based on available data, the classification criteria are not met.

Symptoms related to the physical, chemical and toxicological characteristics The following adverse effects have been noted with therapeutic use of this material: headache; nausea; insomnia; yellow discolouration of the skin; diarrhoea; rash; vomiting.

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
ATOVAQUONE (CAS 95233-18-4)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg and mouse
Chronic		
<i>Oral</i>		
LD	Rat	> 500 mg/kg/day 1 Year
NOAEL	Dog	> 500 mg/kg/day 1 Year
Subacute		
<i>Oral</i>		
LD	Rat	> 500 mg/kg/day 28-Day
BENZYL ALCOHOL (CAS 100-51-6)		
Acute		
<i>Inhalation</i>		
LC50	Rat	1000 ppm
<i>Oral</i>		
LD50	Rat	1230 mg/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Corrosivity

ATOVAQUONE
OECD 404
Result: Negative
Species: Rabbit

Irritation Corrosion - Skin: P.I.I. value

ATOVAQUONE
0

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Eye

ATOVAQUONE
REET
Result: Negative; not likely to be a severe irritant

Eye / Kay and Calandra class - Intact

ATOVAQUONE
3 OECD 405
Result: Minimal irritant
Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization Based on available data, the classification criteria are not met.

Sensitization

ATOVAQUONE

SAR / QSAR, DEREK, Lhasa, UK

Result: Positive

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Mutagenicity

ATOVAQUONE

Ames

Result: Negative

Chromosomal Aberration Assay In Vitro, human lymphocytes

Result: Negative

Mouse Lymphoma Cell Assay

Result: Negative

Carcinogenicity

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Based on available data, the classification criteria are not met.

ATOVAQUONE

24 Month

Result: Negative

Species: Rat

24 Month, Species specific - enzyme induction

Result: Positive

Species: Mouse

Organ: liver

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity

Based on available data, the classification criteria are not met.

Reproductivity

ATOVAQUONE

Pre- and Post-natal development

Result: No effect

Reproduction/Fertility Study

Result: Negative

Species: Rat

Specific target organ toxicity - single exposure

Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure

Due to lack of data the classification is not possible.

Aspiration hazard

Due to lack of data the classification is not possible.

Further information

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

12. Ecological information

Ecotoxicity

Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test Results
ATOVAQUONE (CAS 95233-18-4)			
Aquatic			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	0.0035 mg/l, 48 hours Static test, OECD 202
	NOEC	Water flea (Daphnia magna)	0.0018 mg/l, 48 hours Static test
Microtox	MIC	Aspergillus flavus	> 11 mcg/l
		Azotobacter chroococcum	> 11 mcg/l
		Chaetomium globosum	> 11 mcg/l
		Nostoc sp.	> 11 mcg/l
Other	MIC	Pseudomonas acidovorans	> 11 mcg/l

Components		Species	Test Results
<i>Chronic</i>			
Crustacea	EC50	Water flea (Ceriodaphnia dubia)	0.47 mcg/l, 8 days 7 day static renewal, OPPTS 850.1300
	LOEC	Water flea (Ceriodaphnia dubia)	0.16 mcg/l, 8 days
	NOEC	Water flea (Ceriodaphnia dubia)	0.083 mcg/l, 8 days
Terrestrial			
<i>Acute</i>			
Earthworm	EC50	Manure worm (Eisenia foetida)	> 1000 mg/kg, 14 days , OECD 207
	NOEC	Manure worm (Eisenia foetida)	1000 mg/kg, 14 days Nominal
BENZYL ALCOHOL (CAS 100-51-6)			
Aquatic			
<i>Acute</i>			
Activated Sludge Respiration	IC50	Mixed industrial/residential sludge.	2100 mg/l, 49 hours
Algae	EC50	Green algae (Scenedesmus quadricauda)	640 mg/l, 96 hours
Crustacea	EC50	Water flea (Daphnia magna)	360 mg/l, 48 hours
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	10 mg/l, 96 hours Static test
		Fathead minnow (Adult Pimephales promelas)	460 mg/l, 96 hours Static test
Microtox	EC50	Microtox	63.7 mg/l, 15 minutes

* Estimates for product may be based on additional component data not shown.

Persistence and degradability No data is available on the degradability of this product.

Photolysis

Half-life (Photolysis-aqueous)

ATOVAQUONE 2.63 Hours Measured

Half-life (Photolysis-atmospheric)

BENZYL ALCOHOL 2 Days Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-soil)

ATOVAQUONE 75 %, 1 Day, Soil

Percent degradation (Anaerobic biodegradation)

BENZYL ALCOHOL 100 %, 14 days Serum Bottle, Anaerobic sludge

Bioaccumulative potential No data available for this product.

Partition coefficient n-octanol / water (log Kow)

ATOVAQUONE 5.31

BENZYL ALCOHOL 1.1

Bioconcentration factor (BCF)

BENZYL ALCOHOL 4 Estimated

Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

ATOVAQUONE 3.91 - 4.31 Calculated

Soil/sediment sorption - log Koc

ATOVAQUONE 4.18 - 4.58 Measured

BENZYL ALCOHOL < 0.7 Measured

Mobility in general

Volatility

Henry's law

BENZYL ALCOHOL 0 atm m³/mol, 25 C Estimated

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

UN number	UN3082
UN proper shipping name	Environmentally hazardous substances, liquid, n.o.s. (ATOVAQUONE, FORMULATED PRODUCT), MARINE POLLUTANT
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
Packing group	III
Environmental hazards	
Marine pollutant	Yes
Special precautions for user	May be able to ship as an Excepted or Limited Quantity. Consumer Commodity, ORM-D may apply. See 173.155 and 173.156.
Special provisions	8, 146, 335, IB3, T4, TP1, TP29
Packaging exceptions	155
Packaging non bulk	203
Packaging bulk	241
Qty limits cargo	No limit
Qty limits passenger	No limit
May be able to ship as an Excepted or Limited Quantity. ID 8000, Consumer Commodity, may apply. See Packing Instruction Y963.	

IATA

UN number	UN3082
UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. (ATOVAQUONE, FORMULATED PRODUCT)
Transport hazard class(es)	9
Subsidiary class(es)	-
Packaging group	III
Labels required	Not available.
Environmental hazards	No.
ERG Code	9L
Special precautions for user	May be able to ship as an Excepted or Limited Quantity. ID 8000, Consumer Commodity, may apply. See Packing Instruction Y963.
Other information	
Cargo aircraft only	Allowed.
Passenger & cargo	Allowed.
Additional Information:	
Packaging Instruction	964
Pkg Inst cargo only	964
Pkg Inst passenger & cargo	Y964
SP see 44	A97,A158
Max net qty pkg	450 L
Max net qty pkg cargo only	450 L
Max net qty pkg LQ	30 kg G

IMDG

UN number	UN3082
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (ATOVAQUONE, FORMULATED PRODUCT)
Transport hazard class(es)	
Class	9
Subsidiary risk	-

Packing group III

Environmental hazards

Marine pollutant Yes

EmS F-A, S-F

Special precautions for user May be able to ship as an Excepted or Limited Quantity.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

DOT; IATA; IMDG



Marine pollutant



15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.**US state regulations****US. Massachusetts RTK - Substance List**

BENZYL ALCOHOL (CAS 100-51-6)

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

BENZYL ALCOHOL (CAS 100-51-6)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	06-27-2014
Revision date	06-27-2014
Version #	13
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 0 Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 0 Flammability: 0 Instability: 0
References	GSK Hazard Determination
Disclaimer	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.
Revision Information	Product and Company Identification: Synonyms Other information, including date of preparation or last revision: References