SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	MEPRON SUSPENSION
Registration number	-
Synonyms	MEPRON SUSPENSION 750 MG/5 ML * WELLVONE SUSPENSION 750 MG/5 ML * WELLVONE SUSPENSAO 150 MG/ ML * SAMTIREL * ATOVAQUONE SUSPENSION 750MG/5ML * ATOVAQUONE, FORMULATED PRODUCT
Issue date	27-June-2014
Version number	13
Revision date	27-June-2014
Supersedes date	18-June-2014

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	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.
Uses advised against	No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

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

Classification according to Regulation (EC) No 1272/2008 as amended

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

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

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

Supplemental label information None.

2.3. Other hazards Expected to be non-combustible.
See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
ATOVAQUONE	15	95233-18-4 -	-	-	M=100
Classification:	**DSD:** N;R50-53				
	CLP: Aquatic Acute 1;H400, Aquatic Chronic 1;H410				
Benzyl alcohol	1	100-51-6 202-859-9	-	603-057-00-5	
Classification:	**DSD:** Xn;R20/22, Xi;R36				
	CLP: Acute Tox. 4;H302, Eye Irrit. 2;H319, Acute Tox. 4;H332				
Other components below reportable levels	84.0				

CLP: Regulation No. 1272/2008.
DSD: Directive 67/548/EEC.
M: M-factor
vPvB: very persistent and very bioaccumulative substance.
PBT: persistent, bioaccumulative and toxic substance.
#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

General information In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

4.1. Description of 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.

4.2. Most important symptoms and effects, both 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.

4.3. Indication of any immediate medical attention and special treatment needed Treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards Expected to be non-combustible.

5.1. Extinguishing media

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media None known.

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting procedures Move containers from fire area if you can do so without risk.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. For personal protection, see section 8.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

6.2. Environmental precautions Prevent further leakage or spillage if safe to do so.

6.3. Methods and material 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.

6.4. Reference to other sections

For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid prolonged exposure. Use care in handling/storage.

7.2. 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).

7.3. Specific end use(s)

Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components	Type	Value
ATOVAQUONE (CAS 95233-18-4)	8 HR TWA	200 mcg/m3
	OHC	2

Biological limit values

No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures

Follow standard monitoring procedures.

Derived no-effect level (DNEL)

Not available.

Predicted no effect concentrations (PNECs)

Not available.

8.2. Exposure controls

Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

General information

Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Eye/face protection

If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)

Skin protection

- 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. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other

Wear suitable protective clothing. (EN 14605 for splashes, EN ISO 13982 for dust)

Respiratory protection

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

Hygiene measures

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.

Environmental exposure controls

Hazard guidance and control recommendations

Not available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Physical state	Liquid.
Form	Suspension.
Colour	Not available.
Odour	Not available.
Odour 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.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Solubility (other)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials.
10.5. Incompatible materials	None known.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects. 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.
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	The following adverse effects have been noted with therapeutic use of this material: headache; nausea; insomnia; yellow discolouration of the skin; diarrhoea; rash; vomiting.

11.1. Information on toxicological effects

Components	Species	Test results
ATOVAQUONE (CAS 95233-18-4)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg and mouse
Chronic		
Oral		
LD	Rat	> 500 mg/kg/day 1 Year
NOAEL	Dog	> 500 mg/kg/day 1 Year
Subacute		
Oral		
LD	Rat	> 500 mg/kg/day 28-day
Benzyl alcohol (CAS 100-51-6)		
Acute		
Inhalation		
LC50	Rat	1000 ppm
Oral		
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 sensitisation Due to lack of data the classification is not possible.

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

Sensitisation
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 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

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

Reproductivity
ATOVAQUONE
Pre- and Post-natal development
Result: No effect

Reproductivity

ATOVAQUONE	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.

Mixture versus substance information Not available.

Other 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.

SECTION 12: Ecological information

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

Components		Species	Test results
ATOVAQUONE (CAS 95233-18-4)			
Aquatic			
Acute			
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
Chronic			
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			
Acute			
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			
Acute			
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.

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

Photolysis

Half-life (Photolysis-aqueous)

ATOVAQUONE	2.63 Hours Measured

Photolysis

Half-life (Photolysis-atmospheric)

Benzyl alcohol	2 Days Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-ready)

Benzyl alcohol	> 90 %, 30 days Closed Bottle test, Activated sludge

Percent degradation (Aerobic biodegradation-soil)

ATOVAQUONE	75 %, 1 Day, Soil

Percent degradation (Anaerobic biodegradation)

Benzyl alcohol	100 %, 14 days Serum Bottle, Anaerobic sludge

12.3. 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

12.4. 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 m^3/mol, 25 C Estimated

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste 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.

EU waste code The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal methods/information Collect and reclaim or dispose in sealed containers at licensed waste disposal site. This material and its container must be disposed of as hazardous waste. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

ADR

14.1. UN number UN3082

14.2. UN proper shipping name Environmentally hazardous substance, liquid, n.o.s. (ATOVAQUONE, FORMULATED PRODUCT)

14.3. Transport hazard class(es)

Class 9

Subsidiary risk -

Label(s) 9

Hazard No. (ADR) 90

Tunnel code E

14.4. Packing group III

14.5. Environmental hazards No.

14.6. Special precautions for user May be able to ship as an Excepted or Limited Quantity.
May not be subject to ADR; See SP 601.

Additional information:

LTD QTY index	LQ7
Special Provisions	274, 335, 601

IATA

14.1. UN number	UN3082
14.2. UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. (ATOVAQUONE, FORMULATED PRODUCT)
14.3. Transport hazard class(es)	9
Subsidiary class(es)	-
14.4. Packing group	III
Labels required	Not available.
14.5. Environmental hazards	No.
ERG Code	9L
14.6. 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.
Additional Information:	
Passenger & cargo	Allowed.
Packaging Instruction	964
Pkg Inst cargo only	964
Pkg Inst pasenger & cargo	Y964
LQ	
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

14.1. UN number	UN3082
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (ATOVAQUONE, FORMULATED PRODUCT)
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
14.4. Packing group	III
14.5. Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F
14.6. Special precautions for user	May be able to ship as an Excepted or Limited Quantity.

May be able to ship as an Excepted or Limited Quantity.
ID 8000, Consumer Commodity, may apply. See Packing Instruction Y963.

14.7. Transport in bulk according to Annex II of MARPOL73/78 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.

ADR; IATA; IMDG

Marine pollutant

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not listed.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

BENZYL ALCOHOL (CAS 100-51-6)

Directive 94/33/EC on the protection of young people at work

Not listed.

Other regulations	The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.
National regulations	Not available.
15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations	Not available.
References	GSK Hazard Determination

Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any statements or R-phrases and H-statements under Sections 2 to 15	R20/22 Harmful by inhalation and if swallowed. R36 Irritating to eyes. R50 Very toxic to aquatic organisms. R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R53 May cause long term adverse effects in the aquatic environment. H302 Harmful if swallowed. H319 Causes serious eye irritation. H332 Harmful if inhaled. H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.
Revision information	Product and Company Identification: Synonyms SECTION 16: Other information: References
Training information	Follow training instructions when handling this material.
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.