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	MALARONE TABLETS AND PAEDIATRIC TABLETS
Registration number	-
Synonyms	MALARONE PAEDIATRIC TABLETS 62.5 MG/125 MG * MALARONE JUNIOR TABLETS 62.5 MG/125 MG * NDC NO 0173-0676-01 * ATOVAQUONE AND PROGUANIL HYDROCHLORIDE, FORMULATED PRODUCT
Issue date	28-August-2014
Version number	06
Revision date	28-August-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 Caution - Pharmaceutical agent. 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	51.3	95233-18-4 -	-	-	M=100
Classification:	**DSD:** N;R50-53				
	CLP: Aquatic Acute 1;H400, Aquatic Chronic 1;H410				
PROGUANIL HYDROCHLORIDE	20.52	637-32-1 211-283-7	-	-	
Classification:	**DSD:** T;R25, N;R50/53				
	CLP: Acute Tox. 3;H301, Aquatic Acute 1;H400, Aquatic Chronic 2;H411				
MICROCRYSTALLINE CELLULOSE	5 - < 10	9004-34-6 232-674-9	-	-	
Classification:	**DSD:** -				
	CLP: -				
Polyvinylpyrrolidone	3 - < 5	9003-39-8 -	-	-	
Classification:	**DSD:** R52/53				
	CLP: Aquatic Chronic 3;H412				
MAGNESIUM STEARATE	< 1	557-04-0 209-150-3	-	-	
Classification:	**DSD:** -				
	CLP: -				
Titanium dioxide	< 1	13463-67-7 236-675-5	-	-	
Classification:	**DSD:** -				
	CLP: -				
Other components below reportable levels	10 - < 20				

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. Show this safety data sheet to the doctor in attendance.

4.1. Description of first aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. IF SWALLOWED: Call a POISON CENTRE or doctor/physician 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; gastrointestinal distress; weakness; dizziness; nosebleed; sore throat.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. In case of shortness of breath, give oxygen. Keep victim warm. Keep victim under observation. Symptoms may be delayed.

SECTION 5: Firefighting measures

General fire hazards No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO_2).

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 Use water spray to cool unopened containers.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not touch or walk through spilled material. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. 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 Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up Stop the flow of material, if this is without risk. Collect spillage. Prevent product from entering drains. Following product recovery, flush area with water.

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. Do not taste or swallow. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.

7.2. Conditions for safe storage, including any incompatibilities Store locked up. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. 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
HYDROXYPROPYL CELLULOSE (CAS 9004-64-2)	OHC	1
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	OHC	1
PROGUANIL HYDROCHLORIDE (CAS 637-32-1)	15 MIN STEL	500 mcg/m3
	OHC	2
SODIUM STARCH GLYCOLATE (CAS 9063-38-1)	OHC	1

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	STEL	20 mg/m3	Inhalable dust.
	TWA	4 mg/m3	Respirable dust.
		10 mg/m3	Inhalable dust.
Titanium dioxide (CAS 13463-67-7)	TWA	4 mg/m3	Respirable.
		10 mg/m3	Inhalable

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. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.

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. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended. Chemical respirator with organic vapour cartridge and full facepiece. (eg. EN 166)

Skin protection

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

- Other Avoid contact with clothing.

Respiratory protection No personal respiratory protective equipment normally required. 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 For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. Keep away from food and drink. 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 Contain spills and prevent releases and observe national regulations on emissions. Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state Solid.

Form Tablet.

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	Strong oxidising agents. Fluorine.
10.6. Hazardous decomposition products	No hazardous decomposition products are known. Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.
Information on likely routes of exposure	
Ingestion	Harmful if swallowed.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	No adverse effects due to skin contact are expected.
Eye contact	Direct contact with eyes may cause temporary irritation.
Symptoms	The possible symptoms of overexposure include: headache, gastrointestinal distress, weakness, dizziness, nosebleed, sore throat.

11.1. Information on toxicological effects

Acute toxicity Harmful if swallowed.

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

Components	Species	Test results
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 2000 mg/kg
Polyvinylpyrrolidone (CAS 9003-39-8)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
PROGUANIL HYDROCHLORIDE (CAS 637-32-1)		
Acute		
Oral		
LD50	Rat	58 - 200 mg/kg
Chronic		
Oral		
LD	Rat	200 mg/kg/day, 28 Day In combination with 20mg/kg atovaquone
Titanium dioxide (CAS 13463-67-7)		
Acute		
Inhalation		
LC50	Rat	6820 mcg/m3
Oral		
LD50	Rat	> 24 g/kg
Chronic		
Inhalation		
LOEC	Rat	8.6 mg/m3, 1 years TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophrages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years Highest dose
		5 mg/m3, 24 months
Subacute		
Inhalation		
LOEL	Rat	0.1 - 35 mg/m3, 4 weeks Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.
NOAEC	Guinea pig	26 mg/m3, 3 weeks No evidence of significant inflammation in respiratory tract.
Oral		
NOAEL	Rat	100000 ppm, 14 Day Dietary study, highest dose tested.
Subchronic		
Inhalation		
LOEC	Rat	3.2 - 20 mg/m3, 8 min Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.

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

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Corrosivity

ATOVAQUONE	OECD 404 Result: negative Species: Rabbit

Irritation Corrosion - Skin

TITANIUM DIOXIDE	Acute dermal irritation; OECD 404, Literature data Result: Non-irritant Species: Rabbit Literature data Result: Non-irritant Species: Guinea pig Literature data Result: Non-irritant Species: Human

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

ATOVAQUONE	0
MAGNESIUM STEARATE	0

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye

TITANIUM DIOXIDE	OECD 405, Literature data Result: Mild irritant Species: Rabbit
ATOVAQUONE	REET Result: Negative; not likely to be a severe irritant
PROGUANIL HYDROCHLORIDE	REET Result: Not likely to be a severe irritant

Eye / Kay and Calandra class - Intact

ATOVAQUONE	3 OECD 405 Result: Minimal irritant Species: Rabbit
MAGNESIUM STEARATE	4 Recovery Period: 2 days

Respiratory sensitisation Not applicable.

Skin sensitisation This product is not expected to cause skin sensitisation.

Sensitisation

TITANIUM DIOXIDE	5 % Optimisation Test, Literature data - Vehicle: petrolatum Result: negative Species: Guinea pig Test Duration: 48 hour exposure Patch test, Literature data Result: negative Species: Human
PROGUANIL HYDROCHLORIDE	SAR Result: No structural alerts identified.
ATOVAQUONE	SAR / QSAR, DEREK, Lhasa, UK Result: positive

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

PROGUANIL HYDROCHLORIDE	27.5 - 45 mcg/mL Mouse Lymphoma Cell (L5178Y) Assay Result: negative 74 mcg/mL Ames Result: negative < 45 mg/kg In vivo Micronucleus Result: negative
ATOVAQUONE	Ames Result: negative
TITANIUM DIOXIDE	Ames, Literature data Result: negative
ATOVAQUONE	Chromosomal Aberration Assay In Vitro, human lymphocytes Result: negative
TITANIUM DIOXIDE	Micronucleus Assay in vitro, CHO cells, Literature data Result: negative Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data Result: positive
ATOVAQUONE	Mouse Lymphoma Cell Assay Result: negative
TITANIUM DIOXIDE	Syrian Hamster Embryo (SHE) cell transformation assay Result: negative WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data Result: positive

Carcinogenicity Health injuries are not known or expected under normal use. Titanium Dioxide produced carcinogenic effects in a lifetime study in mice. High concentrations or doses administered over an extended period of time were required to produce adverse effects.

TITANIUM DIOXIDE	0.5 mg/m3, Literature data Result: negative Species: Rat Test Duration: 24 months 0.72 - 14.8 mg/m3, Literature data Result: negative Species: Mouse 10 - 250 mg/m3, Dietary study - Literature data. Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration. Species: Rat Test Duration: 24 months
ATOVAQUONE	24 Month Result: negative Species: Rat 24 Month, Species specific - enzyme induction Result: positive Species: Mouse Organ: liver
TITANIUM DIOXIDE	25000 - 50000 ppm, Dietary study Result: negative Species: Mouse 25000 - 50000 ppm, Dietary study - Literature data. Result: negative Species: Rat 7.2 - 14.8 mg/m3, Literature data Result: Lung tumour Species: Rat Test Duration: 24 months
PROGUANIL HYDROCHLORIDE	Literature search Result: Negative in 24 month study dosed 1.1 times average Human systemic exposure. Species: Rat Literature search Result: Negative in 24 month study dosed 1.5 times average human exposure. Species: Mouse

IARC Monographs. Overall Evaluation of Carcinogenicity

POLYVINYLPYRROLIDONE (CAS 9003-39-8)	3 Not classifiable as to carcinogenicity to humans.
TITANIUM DIOXIDE (CAS 13463-67-7)	2B Possibly carcinogenic to humans.

Reproductive toxicity Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.

Reproductivity

PROGUANIL HYDROCHLORIDE	0.005 - 0.025 % Fertility, dietary administration Result: reduced fertility Species: Rat 20 mg/kg/day Teratogenicity, Maternal deaths at 50mg/kg/day. No other evidence of maternal toxicity were noted and no adverse effect on litter size, dead or reabsorbed foetuses per litter, post implantation loss or foetal body measurments. Result: negative Species: Rat Notes: Administered alone and with atovaquone 2.5:1 30 mg/kg Embryo-foetal development, high incidence of embryo deaths on day 1. no harmful effects on the foetus on days 9 and 13 Species: Rat Notes: Cytoguanil administered
ATOVAQUONE	Pre- and Post-natal development Result: No effect Reproduction/Fertility Study Result: negative Species: Rat

Specific target organ toxicity - single exposure See effects of repeat exposure.

Specific target organ toxicity - repeated exposure Kidneys. Gastrointestinal tract. Lymph nodes. Thymus. Adverse effects might occur in the following organ(s) following overexposure: and bone marrow and formation of blood cells.

Aspiration hazard	Not likely, due to the form of the product.
Mixture versus substance information	No information available.
Other information	Not available.

SECTION 12: Ecological information

12.1. Toxicity Very toxic to aquatic life. The product contains a substance which may cause long-term adverse effects in 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
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
Polyvinylpyrrolidone (CAS 9003-39-8)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours Static test
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	84 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	32 mg/l, 48 hours Static test
PROGUANIL HYDROCHLORIDE (CAS 637-32-1)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	39.8 mg/l, 3 hours OECD 209
Algae	EC50	Green algae (Selenastrum capricornutum)	0.36 mg/l, 72 hours Static test, OECD 201
	NOEC	Green algae (Selenastrum capricornutum)	0.25 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	16.4 mg/l, 48 hours Static test, OECD 202
Fish	EC50	Rainbow trout (Juvenile Oncorhyncus mykiss)	100 mg/l, 96 hours Static renewal test, OECD 203
Chronic			
Crustacea	LOEC	Water flea (Ceriodaphnia dubia)	10 mg/l, 7 days 7 day static renewal, EPA 1002

Components		Species	Test results
	NOEC	Water flea (Ceriodaphnia dubia)	5.6 mg/l, 7 days
Titanium dioxide (CAS 13463-67-7)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours Static test

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

12.2. Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

ATOVAQUONE	2.63 Hours Measured

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE	17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE	210 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

PROGUANIL HYDROCHLORIDE	> 1 years

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

MAGNESIUM STEARATE	77 %, 28 days BOD
PROGUANIL HYDROCHLORIDE	< 4 %, 14 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge
Polyvinylpyrrolidone	0 %, 28 days Modified MITI test, Activated sludge

Percent degradation (Aerobic biodegradation-ready)

MAGNESIUM STEARATE	95 %, 22 days Sturm test
PROGUANIL HYDROCHLORIDE	4.03 %, 28 days

Percent degradation (Aerobic biodegradation-soil)

ATOVAQUONE	75 %, 1 Day, Soil
MAGNESIUM STEARATE	50 %, 13 days

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

ATOVAQUONE	5.31
PROGUANIL HYDROCHLORIDE	1.56

Bioconcentration factor (BCF)

MAGNESIUM STEARATE	> 9999 Estimated

12.4. Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

ATOVAQUONE	3.91 - 4.31 Calculated
PROGUANIL HYDROCHLORIDE	2.5 Measured, pH 7

Soil/sediment sorption - log Koc

ATOVAQUONE	4.18 - 4.58 Measured
MAGNESIUM STEARATE	5.86 Estimated

Mobility in general

Volatility

Henry's law

PROGUANIL HYDROCHLORIDE	0 atm m^3/mol, 25 C Estimated

Distribution

Octanol/water distribution coefficient log DOW

PROGUANIL HYDROCHLORIDE	0.99, pH 5 0.99, pH 7 1.56, pH 9

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. Since emptied containers may retain product residue, follow label warnings even after container is emptied.
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. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose in accordance with all applicable regulations.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

14.1. UN number	UN3077
14.2. UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (ATOVAQUONE AND PROGUANIL HYDROCHLORIDE, 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	Not available.

IATA

14.1. UN number	UN3077
14.2. UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (ATOVAQUONE AND PROGUANIL HYDROCHLORIDE, FORMULATED PRODUCT)
14.3. Transport hazard class(es)	9
Subsidiary class(es)	-
14.4. Packing group	III
Labels required	9
14.5. Environmental hazards	No.
ERG Code	9L
14.6. Special precautions for user	Not available.
Other information	
Cargo aircraft only	Allowed.
Additional Information:	
Passenger & cargo	Allowed.

IMDG

14.1. UN number	UN3077
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ATOVAQUONE AND PROGUANIL HYDROCHLORIDE, FORMULATED PRODUCT)
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
14.4. Packing group	III
14.5. Environmental hazards	
Marine pollutant	No.
EmS	F-A, S-F
14.6. Special precautions for user	Not available.

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

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

Not listed.

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	Follow national regulation for work with chemical agents.
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	R22 Harmful if swallowed. R25 Toxic if swallowed. R50 Very toxic to aquatic organisms. R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R53 May cause long term adverse effects in the aquatic environment. H301 Toxic if swallowed. H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects. H411 Toxic to aquatic life with long lasting effects. H412 Harmful to aquatic life with long lasting effects.
Revision information	This document has undergone significant changes and should be reviewed in its entirety.
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.