SAFETY DATA SHEET

1. Identification

Product identifier **MALARONE TABLETS AND PAEDIATRIC TABLETS**

Other means of identification

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

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)CYCLOHEXYL)-3-HYDROXY-1,4-NAPHTHOQUINONE * 1672 (GW ACN)	95233-18-4	51.3
PROGUANIL HYDROCHLORIDE	336U50 * 1-(4-CHLOROPHENYL)-5-ISOPROPYLBIGUANIDE HYDROCHLORIDE * CHLOROGUANIDE HYDROCHLORIDE * PALUDRINE HYDROCHLORIDE * IMIDODICARBONIMIDIC DIAMIDE, N-(4-CHLOROPHENYL)-N'-(1-METHYLETHYL)-, MONOHYDROCHLORIDE * 1659 (GW ACN) * AH7673A * PROGUANILHYDROCHLORIDE	637-32-1	20.52

Chemical name	Common name and synonyms	CAS number	%
HYDROXYPROPYL CELLULOSE	CELLULOSE, 2-HYDROXYPROPYL ETHER * CELLULOSE HYDROXYPROPYL ETHER * 2-HYDROXYPROPYL CELLULOSE * HYDROXYPROPYL CELLULOSE ETHER * HYDROXYPROPYL ETHER OF CELLULOSE * OXYPROPYLATED CELLULOSE * KLUCEL * HPC * HYDROPROPYL CELLULOSE * OHS11282 * RTECS NF9050000	9004-64-2	9.44
MICROCRYSTALLINE CELLULOSE	AVICEL PH MICROCRYSTALLINE CELLULOSE * ABICEL * ALPHA-CELLULOSE * ARBOCEL * ARBOCELL B 600/30 * ARBOCELL BC 200 * AVICEL PH101 * AVICEL PH102 * AVICEL PH103 * AVICEL PH105 * AVICEL PH112 * AVICEL PH200 * BETA-AMYLOSE * CELLEX MX * CELLULOSE (8CI9CI) * CELLULOSE 248 * CELLULOSE CRYSTALLINE * CELLULOSE, FOOD GRADE * CELUFI * CRYSTALLINE CELLULOSE * EMOCEL * MCC * MICROCRYSTALLINE CELLULOSE * POWDERED CELLULOSE * RTECS FJ5691460 * SOLKA FLOC BW200 * CELLULOSA (FIBRA PAPEL) * CELLULOSE (PAPER FIBRES) * CELLULOSE-PAPER FIBER * CELULOSA (FIBRA PAPEL) * TSELLULOOS	9004-34-6	7.8
POLYVINYLPYRROLIDONE	1-ETHENYL-2-PYRROLIDINONE HOMOPOLYMER * POLY(N-VINYLPYRROLIDONE) * PLASDONE	9003-39-8	4.1
SODIUM STARCH GLYCOLATE	STARCH, CARBOXYMETHYL ETHER, SODIUM SALT * CARBOXYMETHYL STARCH SODIUM SALT * EXPLOTAB * SODIUM CARBOXYMETHYL STARCH * SODIUM CM-STARCH * 738 (GW ACN) * CARBOXYMETHYLSTÄRKE, NATRIUMSALZ * SODIUM STARCH GLYCOLATE	9063-38-1	2.87
POLYETHYLENE GLYCOL 400	PEG 400 * ALPHA-HYDRO-OMEGA-HYDROXY-POLY(OXY-1,2-ETHANEDIYL) * PEG * CARBOWAX * POLYOXYETHYLENE 400 * CARBOWAX POLYETHYLENE GLYCOL 400 * CARBOWAX PEG 400 * OHS19121 * RTECS TQ3675000 * GLYCOLS, POLYETHYLENE * POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-HYDRO-.OMEGA. * POLYETHYLENEGLYCOL 6000 * POLYETHYLENGLYKOLE (PEG) (MOLMASSE 200-600)	25322-68-3	0.9
TITANIUM DIOXIDE	TITANIUM OXIDE * TITANIUM(IV) OXIDE * TITANIUM PEROXIDE (TiO2) * PIGMENT WHITE 6	13463-67-7	< 1
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT * MAGNESIUM DISTEARATE * DIBASIC MAGNESIUM STEARATE * MAGNESIUM DISTEARATE, PURE	557-04-0	0.49

Chemical name	Common name and synonyms	CAS number	%
POLYETHYLENE GLYCOL 300	ALPHA-HYDRO-OMEGA-HYDROXY-POLY(OXY-1,2-ETHANEDIYL) * GLYCOLS, POLYETHYLENE * CARBOWAX 300 * PEG 300 * POLY(ETHYLENE ETHER)GLYCOL * POLYETHYLENE GLYCOL * ETHYLENE GLYCOL HOMOPOLYMER * ETHYLENE GLYCOL POLYMER * RTECS TQ3630000 * POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-HYDRO-.OMEGA. * POLYETHYLENEGLYCOL 6000 * POLYETHYLENGLYKOLE (PEG) (MOLMASSE 200-600)	25322-68-3	0.16
Other components below reportable levels			1 - < 3

*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 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 CENTER or doctor/physician 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; gastrointestinal distress; weakness; dizziness; nosebleed; sore throat.

Indication of 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.

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.

5. Fire-fighting measures

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

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 Use water spray to cool unopened containers.

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

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Stop the flow of material, if this is without risk. Collect spillage. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.

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.

7. Handling and storage

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.

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).

8. Exposure controls/personal protection

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
POLYETHYLENE GLYCOL 400 (CAS 25322-68-3)	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

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	15 mg/m3	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total

US. AIHA Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
POLYETHYLENE GLYCOL 300 (CAS 25322-68-3)	TWA	10 mg/m3	Particulate.

US. AIHA Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
POLYETHYLENE GLYCOL 400 (CAS 25322-68-3)	TWA	10 mg/m3	Particulate.

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

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

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended. Chemical respirator with organic vapor cartridge and full facepiece.

Hand protection Wear appropriate chemical resistant gloves.

Skin protection

Other Avoid contact with clothing.

Respiratory protection No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations 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.

9. Physical and chemical properties

Appearance

Physical state Solid.

Form Tablet.

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	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use. Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents. Fluorine.
Hazardous decomposition products	No hazardous decomposition products are known. Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

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 related to the physical, chemical and toxicological characteristics	The possible symptoms of overexposure include: headache, gastrointestinal distress, weakness, dizziness, nosebleed, sore throat.

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
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
POLYETHYLENE GLYCOL 300 (CAS 25322-68-3)		
Acute		
Oral		
LD50	Rat	> 20 g/kg

Components	Species	Test Results
POLYETHYLENE GLYCOL 400 (CAS 25322-68-3)		
Acute		
Oral		
LD50	Rat	30.2 g/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 or skin sensitization

Respiratory sensitization Not applicable.

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

Sensitization

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

Mutagenicity

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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

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

Reproductivity

PROGUANIL HYDROCHLORIDE	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.

12. Ecological information

Ecotoxicity 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

Components		Species	Test Results
POLYETHYLENE GLYCOL 300 (CAS 25322-68-3)			
Aquatic			
Acute			
Fish	LC50	Atlantic salmon (Salmo salar)	> 1000 mg/l, 96 hours
		Crucian carp (Carassius carassius)	> 20000 mg/l, 96 hours
		Rainbow trout,donaldson trout (Oncorhynchus mykiss)	> 20000 mg/l, 96 hours
POLYETHYLENE GLYCOL 400 (CAS 25322-68-3)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	53000 mg/l, 48 hours
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	87000 mg/l, 96 hours
Microtox	EC50	Microtox	100000 mg/l, 15 minutes
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
	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.

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
POLYETHYLENE GLYCOL 400	40.2 - 70 %, 20 Days BOD20
POLYVINYLPYRROLIDONE	0 %, 28 days Modified MITI test, Activated sludge
PROGUANIL HYDROCHLORIDE	< 4 %, 14 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

Percent degradation (Aerobic biodegradation-soil)

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

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

ATOVAQUONE	5.31
PROGUANIL HYDROCHLORIDE	1.56

Bioconcentration factor (BCF)

MAGNESIUM STEARATE	> 9999 Estimated

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

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions 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.

Local disposal regulations Dispose in accordance with all applicable regulations.

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. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN number UN3077

UN proper shipping name Environmentally hazardous substances, solid, n.o.s. (ATOVAQUONE AND PROGUANIL HYDROCHLORIDE, FORMULATED PRODUCT)

Transport hazard class(es)

Class 9

Subsidiary risk -

Label(s)	9
Packing group	III
Special precautions for user	Not available.
Special provisions	8, 146, 335, A112, B54, IB8, IP3, N20, T1, TP33
Packaging exceptions	155
Packaging non bulk	213
Packaging bulk	240

IATA

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

IMDG

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

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

15. Regulatory information

US federal regulations One or more components are not listed on TSCA.

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 - Yes
Delayed Hazard - Yes
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

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
TITANIUM DIOXIDE (CAS 13463-67-7)

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

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
TITANIUM DIOXIDE (CAS 13463-67-7)

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

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
TITANIUM DIOXIDE (CAS 13463-67-7)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

TITANIUM DIOXIDE (CAS 13463-67-7) Listed: September 2, 2011

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 08-28-2014

Revision date	08-28-2014
Version #	06
Further information	HMIS® is a registered trade and service mark of the NPCA. Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.
HMIS® ratings	Health: 2* Flammability: 1 Physical hazard: 0
NFPA ratings	Health: 2 Flammability: 1 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	This document has undergone significant changes and should be reviewed in its entirety.