SAFETY DATA SHEET

1. Identification

Product identifier **WELLVONE TABLETS**

Other means of identification Not available.

Synonym(s) WELLVONE TABLETS 250 MG * 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

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
ATOVAQUONE	566C80 GR151218X TRANS-2(4-(4-CHLOROPHENYL)CYCLOHE 1672 (GW ACN)	95233-18-4	73

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
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	8.26
POLYVINYLPYRROLIDONE	2-PYRROLIDINONE, 1-ETHENYL, HOMOPOLYMER 1-ETHENYL-2-PYRROLIDINONE HOMOPOLYMER 2-PYRROLIDINONE, 1-VINYL-, POLYMERS 1-VINYL-2-PYRROLIDINONE POLYMERS POLY(VINYLPYRROLIDINONE) POLY(N-VINYLPYRROLIDINONE) POLY(1-VINYLPYRROLIDINONE) POLY(VINYLPYRROLIDONE) POLY(N-VINYLPYRROLIDONE) POVIDONE PVP VINYLPYRROLIDINONE POLYMER N-VINYLPYRROLIDINONE POLYMER N-VINYLPYRROLIDONE HOMOPOLYMER VINYLPYRROLIDONE POLYMER N-VINYLPYRROLIDONE POLYMER RTECS TR8370000 PLASDONE PLASDONE K29/32 POLY-1-VINYL-2-PYRROLIDON POLYVINYL-PYRROLIDONE PROVIDONE	9003-39-8	3.51
MAGNESIUM STEARATE	OCTADECANOIC ACID, MAGNESIUM SALT STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE OCTADECANOIC ACID MAGNESIUM SALT MAGNESIUM OCTADECANOATE C36H70MGO4 OHS13505 RTECS WI4390000 MAGNESIUMDISTEARAT	557-04-0	0.5
POLYETHYLENE GLYCOL 8000	POLYOXYETHYLENE 8000 POLYGLYCOL E-8000	25322-68-3	0.2
Other components below reportable levels			14.53

*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 plenty of water. If skin irritation or rash occurs: Get medical advice/attention. For minor skin contact, avoid spreading material on unaffected skin.

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

Ingestion Rinse mouth. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed May cause allergic skin reaction.

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically.

General information Wash contaminated clothing before reuse.

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 In the event of fire, cool tanks with water spray.

Specific methods Cool containers exposed to flames with water until well after the fire is out.

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 personal protective equipment. 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 MSDS.

Methods and materials for containment and cleaning up This material is classified as a water pollutant under the Clean Water Act and should be prevented from contaminating soil or from entering sewage and drainage systems which lead to waterways. Stop the flow of material, if this is without risk. Collect spillage. Following product recovery, flush area with water. For waste disposal, see section 13 of the MSDS.

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 contact with skin. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.

Conditions for safe storage, including any incompatibilities 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 MSDS).

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
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	OHC	1
POLYETHYLENE GLYCOL 8000 (CAS 25322-68-3)	OHC	1
POLYVINYLPYRROL IDONE (CAS 9003-39-8)	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.

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

US. NIOSH: Pocket Guide to Chemical Hazards

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

US. AIHA Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
POLYETHYLENE GLYCOL 8000 (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.

Individual protection measures, such as personal protective equipment

Eye/face protection Not available.

Hand protection The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.

Other Not normally needed.

Respiratory protection No personal respiratory protective equipment normally required.

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.

9. Physical and chemical properties

Appearance

Physical state Solid.

Form Solid.

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)	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	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents. Fluorine.
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	Expected to be a low ingestion hazard.
Inhalation	Not expected to occur during normal handling of this product.
Skin contact	May cause an allergic skin reaction.
Eye contact	Health injuries are not known or expected under normal use.
Symptoms related to the physical, chemical and toxicological characteristics	Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting. and yellow discolouration of the skin, insomnia, diarrhoea, Rash.

Information on toxicological effects

Acute toxicity May cause allergic skin reaction.

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

Components	Species	Test Results
Oral		
LD50	Rat	> 2000 mg/kg
POLYETHYLENE GLYCOL 8000 (CAS 25322-68-3)		
Acute		
Oral		
LD50	Rat	> 20 g/kg
POLYVINYLPYRROLIDONE (CAS 9003-39-8)		
Acute		
Oral		
LD50	Rat	> 5000 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
MAGNESIUM STEARATE — 0

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

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

Skin sensitization May cause an allergic skin reaction.

Sensitization

ATOVAQUONE — SAR / QSAR, DEREK, Lhasa, UK
Result: Positive

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

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

IARC Monographs. Overall Evaluation of Carcinogenicity

POLYVINYLPYRROLIDONE (CAS 9003-39-8) — 3 Not classifiable as to carcinogenicity to humans.

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

ATOVAQUONE — Pre- and Post-natal development
Result: No effect
Reproduction/Fertility Study
Result: Negative
Species: Rat

Specific target organ toxicity - single exposure Not available.

Specific target organ toxicity - repeated exposure Not available.

Aspiration hazard Not likely, due to the form of the product.

12. Ecological information

Ecotoxicity Very toxic to aquatic life.

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
Microtox	EC50	Microtox	12.5 mg/l, 15 minutes
POLYETHYLENE GLYCOL 8000 (CAS 25322-68-3)			
Aquatic			
Acute			
Fish	EC50	Goldfish (Adult Carassius auratus)	> 50000 mg/L, 24 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

* 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

Biodegradability

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

Bioconcentration factor (BCF)

MAGNESIUM STEARATE	> 9999 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
MAGNESIUM STEARATE	5.86 Estimated

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions 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.

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, FORMULATED PRODUCT), MARINE POLLUTANT
Transport hazard class(es)	9
Subsidiary class(es)	Not available.
Packing group	III
Special precautions for user	May be able to ship as an Excepted or Limited Quantity. Review all HazMat Table packaging exceptions and instructions to identify options. Consumer Commodity, ORM-D may apply.See 173.155.
Labels required	9
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, FORMULATED PRODUCT)
Transport hazard class(es)	9
Subsidiary class(es)	-
Packaging group	III
Environmental hazards	No
Labels required	Not available.
ERG Code	9L
Special precautions for user	May be able to ship as an Excepted or Limited Quantity. Review all HazMat Table packaging exceptions and instructions to identify options. ID 8000, Consumer Commodity, may apply. See Packing Instruction Y963.

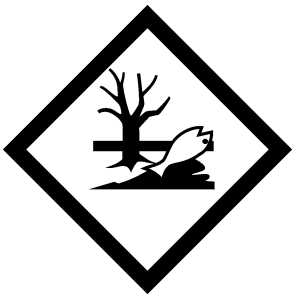
IMDG

UN number	UN3077
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ATOVAQUONE, FORMULATED PRODUCT)
Transport hazard class(es)	9
Subsidiary class(es)	-
Packaging group	III
Environmental hazards	
Marine pollutant	Yes
Labels required	Not available.

EmS	F-A, S-F
Special precautions for user	May be able to ship as an Excepted or Limited Quantity. Review all HazMat Table packaging exceptions and instructions to identify options. May be exempt from IMDG regulations.See SP 335.
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.
General information	DOT Regulated Marine Pollutant. IMDG Regulated Marine Pollutant.

DOT; IATA; IMDG

Marine pollutant



15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

SARA 304 Emergency release notification

Not regulated.

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	No
SARA 311/312 Hazardous chemical	No

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.

DEA Essential Chemical Code Number

Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

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 this product complies 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 06-06-2013

Revision date 06-06-2013

Version # 04

Further information This material has not been assessed for HMIS or NFPA ratings.

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: Product and Company Identification
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties:
Transport Information: Proper Shipping Name/Packing Group
Regulatory Information: Risk Phrases - Class.
GHS: Classification