



SAFETY DATA SHEET

1. Identification

Product identifier VOTRIENT TABLETS

Other means of identification

Synonyms

VOTRIENT TABLETS 50 MG * VOTRIENT TABLETS 100 MG * VOTRIENT TABLETS 200 MG *
VOTRIENT TABLETS 400 MG * VOTRIENT TABLETS 500 MG * GW786034B TABLETS *
PAZOPANIB 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	%
PAZOPANIB HYDROCHLORIDE	5-({4-[2,3-DIMETHYL-2H-INDAZOL-6-YL]METHYLAMINO}PHENOXY)-2-METHYLBENZENESULFONAMIDE HYDROCHLORIDE * GW786034B * SB-710468-A	635702-64-6	52.0 - 70.0

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	18.0 - 37.0
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	4.0 - 7.0
POLYVINYLPIRROLIDONE	1-ETHENYL-2-PYRROLIDINONE HOMOPOLYMER * POLY(N-VINYLPYRROLIDONE) * PLASDONE	9003-39-8	2.0 - 5.0
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT * MAGNESIUM DISTEARATE * DIBASIC MAGNESIUM STEARATE * MAGNESIUM DISTEARATE, PURE	557-04-0	<1.0
TITANIUM DIOXIDE	TITANIUM OXIDE * TITANIUM(IV) OXIDE * TITANIUM PEROXIDE (TiO2) * PIGMENT WHITE 6	13463-67-7	<1.0
Other components below reportable levels			<3.0

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

4. First-aid measures

Inhalation	In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention immediately.
Skin contact	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Take off immediately all contaminated clothing. Get medical attention if symptoms occur.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Rinse with water.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
Most important symptoms/effects, acute and delayed	The following adverse effects have been noted with therapeutic use of this material: diarrhoea, headache, vomiting, increased blood pressure, nausea, symptoms of hypersensitivity (such as skin rash, hives, itching).
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.
General information	Take off all contaminated clothing immediately. 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. Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire-fighting equipment/instructions	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	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 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	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. Provide adequate ventilation. Should be handled in closed systems, if possible. Pregnant or breastfeeding women must not handle this product. 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	Note
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1	
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	OHC	1	
PAZOPANIB HYDROCHLORIDE (CAS 635702-64-6)	8 HR TWA	250 mcg/m ³	
	OHC	2	REPRODUCTIVE HAZARD
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/m ³	Respirable fraction.
		15 mg/m ³	Total dust.

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

Components	Type	Value	Form
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

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Explosion-proof general and local exhaust ventilation. 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	Chemical goggles are recommended.
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.
Skin protection	
Other	Not normally needed.
Respiratory protection	If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn.
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. When using do not smoke. Wash hands after handling and before eating. An occupational/industrial hygiene monitoring method has been developed for this material. New or expectant mothers might be at greater risk from overexposure. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices.

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	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Health injuries are not known or expected under normal use. May be harmful if swallowed.
Inhalation	Health injuries are not known or expected under normal use. Inhalation of dusts may cause respiratory irritation.
Skin contact	Health injuries are not known or expected under normal use. Dust or powder may irritate the skin.
Eye contact	Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.

Symptoms related to the physical, chemical and toxicological characteristics	The following adverse effects have been noted with therapeutic use of this material: diarrhoea; headache; vomiting; increased blood pressure; nausea; symptoms of hypersensitivity (such as skin rash, hives, itching). Adverse effects might occur in the following organ(s) following overexposure: liver.
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Information on toxicological effects

Acute toxicity	Health injuries are not known or expected under normal use. Adverse effects might occur with repeated ingestion.
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Components	Species	Test Results
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 2000 mg/kg

Components	Species	Test Results
<i>Oral</i> LD50	Rat	> 2000 mg/kg
PAZOPANIB HYDROCHLORIDE (CAS 635702-64-6)		
Acute		
<i>Oral</i> LD50	Rat	> 2000 mg/kg
Chronic		
<i>Oral</i> NOAEL	Monkey	50 mg/kg/day, 1 yr
POLYVINYLPIRROLIDONE (CAS 9003-39-8)		
Acute		
<i>Oral</i> LD50	Rat	> 5000 mg/kg
TITANIUM DIOXIDE (CAS 13463-67-7)		
Acute		
<i>Inhalation</i> LC50	Rat	6820 mcg/m3
<i>Oral</i> LD50	Rat	> 24 g/kg
Chronic		
<i>Inhalation</i> LOEC	Rat	8.6 mg/m3, 1 years TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years Highest dose 5 mg/m3, 24 months
Subacute		
<i>Inhalation</i> 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.
<i>Oral</i> NOAEL	Rat	100000 ppm, 14 Day Dietary study, highest dose tested.
Subchronic		
<i>Inhalation</i> 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 Health injuries are not known or expected under normal use.

Irritation Corrosion - Skin

TITANIUM DIOXIDE	Acute dermal irritation; OECD 404, Literature data Result: Non-irritant Species: Rabbit
PAZOPANIB HYDROCHLORIDE	Acute dermal irritation; OECD 404, Primary dermal irritation index = 0 Result: Negative
TITANIUM DIOXIDE	Literature data Result: Non-irritant Species: Guinea pig

Irritation Corrosion - Skin		
TITANIUM DIOXIDE		Literature data Result: Non-irritant Species: Human
Irritation Corrosion - Skin: P.I.I. value		
MAGNESIUM STEARATE		0
Serious eye damage/eye irritation	Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.	
Eye		
PAZOPANIB HYDROCHLORIDE		Acute ocular irritation; OECD 405, Kay and Calandra score = 4 Result: Mild irritant Species: Rabbit IRE Assay Result: Negative; not likely to be a severe irritant Species: Rabbit
TITANIUM DIOXIDE		OECD 405, Literature data Result: Mild irritant Species: Rabbit
Eye / Kay and Calandra class - Intact		
MAGNESIUM STEARATE		4 Recovery Period: 2 days
Respiratory or skin sensitization		
Respiratory sensitization	Not available.	
Skin sensitization	Health injuries are not known or expected under normal use. Allergic skin reactions might occur following repeated contact with this material in susceptible individuals.	
Sensitization		
TITANIUM DIOXIDE		5 % Optimisation Test, Literature data - Vehicle: petrolatum Result: Negative Species: Guinea pig Test Duration: 48 hour exposure
PAZOPANIB HYDROCHLORIDE		OECD 429 / Local Lymph Node Assay, Maximum concentration = 25%; vehicle = acetone:olive oil 4:1 Result: Negative Species: Mouse Occupational exposure Result: Positive (limited number of reported cases) Species: Human
TITANIUM DIOXIDE		Patch test, Literature data Result: Negative Species: Human
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Mutagenicity		
PAZOPANIB HYDROCHLORIDE		Ames Assay, GLP assay Result: Negative
TITANIUM DIOXIDE		Ames, Literature data Result: Negative
PAZOPANIB HYDROCHLORIDE		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
PAZOPANIB HYDROCHLORIDE		Micronucleus Assay, GLP assay; maximum dose = 2000 mg/kg (oral) Result: Negative Species: Rat
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

Suspected of causing cancer. Health injuries are not known or expected under normal use.
Contains a material (titanium dioxide) classified as a carcinogen by external agencies.

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
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
SAR / QSAR
Result: Negative

PAZOPANIB HYDROCHLORIDE

IARC Monographs. Overall Evaluation of Carcinogenicity

POLYVINYLPIRROLIDONE (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

Suspected of damaging fertility or the unborn child.

Reproductivity

PAZOPANIB HYDROCHLORIDE

Embryo-foetal development - Oral
Result: Foetal NOAEL = 1 mg/kg/day; cardiac malformations and delayed ossification with doses \geq 3 mg/kg/day; foetal resorption and embryo lethality with dose = 10 mg/kg/day; NOAEL for maternal toxicity = 3 mg/kg/day
Species: Rat
Embryo-foetal development - Oral
Result: Foetal NOAEL not identified; decreased foetal weight with doses \geq 3 mg/kg/day; increased foetal resorption with doses \geq 10 mg/kg/day; NOAEL for maternal toxicity = 10 mg/kg/day
Species: Rabbit
Fertility, Female
Result: Decreased corpora lutea and increased ovarian cysts with doses \geq 100 mg/kg/day (13 weeks)
Species: Mouse
Fertility, Female
Result: Ovarian atrophy with doses \geq 300 mg/kg/day (26 weeks)
Species: Rat
Fertility, Female
Result: Reduced fertility with increased pre-implantation loss, increased rate of foetal resorption with doses \geq 30 mg/kg/day
Species: Rat
Fertility, Male
Result: No effect on mating or fertility; NOAEL = 3 mg/kg/day; changes in sperm counts and other male reproductive tract parameters at doses \geq 3 mg/kg/day
Species: Rat

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure Causes damage to organs through prolonged or repeated exposure. Adverse effects might occur in the following organ(s) following overexposure: liver.
PAZOPANIB HYDROCHLORIDE Repeat dose non-clinical studies; clinical observation
 Organ: Liver

Aspiration hazard Not available.

Chronic effects Causes damage to organs through prolonged or repeated exposure.

Further information Not available.

12. Ecological information

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

Components		Species	Test Results
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
PAZOPANIB HYDROCHLORIDE (CAS 635702-64-6)			
Aquatic			
<i>Acute</i>			
Activated Sludge Respiration	IC50	Residential sludge	> 1083 mg/l, 3 hours Nominal, OECD 209
Algae	EC50	Green algae (Desmodesmus subspicatus)	> 0.46 mg/l, 72 hours Measured, OECD 201
	NOEC	Green algae (Desmodesmus subspicatus)	0.46 mg/l
Crustacea	EC50	Water flea (Daphnia magna)	> 2.9 mg/l, 48 hours Static renewal test, OECD 202
	NOEC	Water flea (Daphnia magna)	2.9 mg/l
<i>Chronic</i>			
Crustacea	EC50	Water flea (Daphnia magna)	0.3 mg/l, 21 days Static renewal test, OECD 211
	LOEC	Water flea (Daphnia magna)	0.54 mg/l, 21 days
	NOEC	Water flea (Daphnia magna)	0.16 mg/l, 21 days
Fish	Growth test LC50	Fathead minnow (Juvenile Pimephales promelas)	> 0.33 mg/l, 28 days Static renewal test, OECD 210
	Growth test LOEC	Fathead minnow (Juvenile Pimephales promelas)	> 0.33 mg/l, 28 days
	Growth test NOEC	Fathead minnow (Juvenile Pimephales promelas)	0.33 mg/l, 28 days
Other	EC50	Chironomid (Chironomus riparius)	> 1000 mg/kg, 28 days Nominal, OECD 218
	LOEC	Chironomid (Chironomus riparius)	> 1000 mg/kg, 28 days
	NOEC	Chironomid (Chironomus riparius)	1000 mg/kg, 28 days
POLYVINYLPIRROLIDONE (CAS 9003-39-8)			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours Static test
Aquatic			
<i>Acute</i>			
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

Components	Species	Test Results
TITANIUM DIOXIDE (CAS 13463-67-7)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) > 1000 mg/l, 48 hours Static test
Persistence and degradability		
Photolysis		
Half-life (Photolysis-atmospheric)		
MAGNESIUM STEARATE		17 Hours Estimated
UV/visible spectrum wavelength		
MAGNESIUM STEARATE		210 nm
Biodegradability		
Percent degradation (Aerobic biodegradation-inherent)		
MAGNESIUM STEARATE		77 %, 28 days BOD
PAZOPANIB HYDROCHLORIDE		0 %, 28 days Modified MITI (II) Test., Activated sludge
		4 %, 28 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge
		50 %, Aquatic sediment, OECD 308
		Result: > 1 year
POLYVINYLPIRROLIDONE		0 %, 28 days Modified MITI test, Activated sludge
Percent degradation (Aerobic biodegradation-soil)		
MAGNESIUM STEARATE		50 %, 13 days
Bioaccumulative potential		
Partition coefficient n-octanol / water (log Kow)		
PAZOPANIB HYDROCHLORIDE		3.65 (Calculated).
Bioconcentration factor (BCF)		
MAGNESIUM STEARATE		> 9999 Estimated
PAZOPANIB HYDROCHLORIDE		5 - 6 , OECD 305, Measured Species: Rainbow trout (Adult Oncorhynchus mykiss)
Mobility in soil		
Adsorption		
Sludge/biomass distribution coefficient - log Kd		
PAZOPANIB HYDROCHLORIDE		0.01, pH 6
Soil/sediment sorption - log Koc		
MAGNESIUM STEARATE		5.86 Estimated
Mobility in general		
Distribution		
Octanol/water distribution coefficient log DOW		
PAZOPANIB HYDROCHLORIDE		2.26, pH 5 3.33, pH 7 3.92, pH 9
Other adverse effects	Not available.	
13. Disposal considerations		
Disposal instructions	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. Collect and reclaim or dispose in sealed containers at licensed waste disposal site.	
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. (PAZOPANIB HYDROCHLORIDE, FORMULATED PRODUCT), MARINE POLLUTANT
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
Packing group	III
Environmental hazards	
Marine pollutant	Yes
Special precautions for user	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. (PAZOPANIB 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

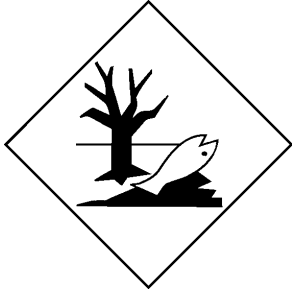
UN number	UN3077
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (PAZOPANIB HYDROCHLORIDE, FORMULATED PRODUCT)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
Packing group	III
Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F
Special precautions for 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



Marine pollutant



General information DOT Regulated Marine Pollutant. IMDG Regulated Marine Pollutant.

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 - No
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** 08-29-2014**Revision date** 08-29-2014**Version #** 16**HMIS® ratings** Health: 1*
Flammability: 0
Physical hazard: 0**NFPA ratings** Health: 1
Flammability: 0
Instability: 0**References** GSK Hazard Determination**Disclaimer** The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.**Revision Information** This document has undergone significant changes and should be reviewed in its entirety.