

SAFETY DATA SHEET



1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material	VOTRIENT TABLETS
Synonym(s)	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
Company Name	<p>GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK</p> <p>UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333 Medical Emergency +1-612-221-3999, Ext 221 Information and Advice: US number, available 24 hours Multi-language response</p> <p>GlaxoSmithKline Corporate Environment, Health & Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US</p> <p>US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response</p>

* 2. HAZARDS IDENTIFICATION

Fire and Explosion Hazards

Expected to be non-combustible.

Health

Caution - Pharmaceutical agent.
 May produce adverse effects on the development of human offspring.
 May produce adverse effects on human fertility.
 May produce allergic skin reactions. Assessment based on limited information. Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching).
 Exposure might occur via skin; eyes; ingestion.
 Health effects information is based on hazards of components.

Environment

This material contains an active pharmaceutical ingredient that may have reproductive or developmental effects on environmental organisms.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
PAZOPANIB HYDROCHLORIDE	635702-64-6	52.5 to 70	
Other components below reportable levels		30.0 to 47.5	

4. FIRST-AID MEASURES

Ingestion

Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.

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Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin contact	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.
Medical Conditions Caused or Aggravated by Exposure	None for occupational exposure.
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.
Extinguishing Media	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	No specific decontamination or detoxification procedures have been identified for this product.

7. HANDLING AND STORAGE

HANDLING

General Requirements Avoid breaking or crushing tablets.

STORAGE

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

OCCUPATIONAL EXPOSURE LIMITS

INGREDIENT	PAZOPANIB HYDROCHLORIDE	
GSK Occupational Hazard Category	2	
GSK Occupational Exposure Limit	250 mcg/m ³ (8 HR TWA)	REPRODUCTIVE HAZARD

ENGINEERING CONTROLS

Containment	Open handling may result in overexposure.
Ventilation	Local exhaust ventilation (LEV) should be used in conjunction with other control measures as a means of removing material incidentally released.
Administrative	Entry to the working area should be controlled. Restrict access to authorised personnel.

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Other Equipment or Procedures Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form Tablet.

10. STABILITY AND REACTIVITY

Stability This product is expected to be stable.

Conditions to Avoid None for normal handling of this product.

* 11. TOXICOLOGY INFORMATION

Pharmacological Effects This preparation contains ingredient(s) with the following activity: a kinase inhibitor.

Target Organ Effects No specific target organ effects have been identified.

Routes of Exposure

Oral Toxicity Not expected to be toxic following ingestion.

Inhalation Toxicity No studies have been conducted.

Skin Effects Irritation is not expected following direct contact.

Eye Effects Irritation is not expected following direct contact with eyes.

Sensitisation Allergic skin reactions might occur following repeated contact with this material in susceptible individuals. Assessment based on limited information.

Genetic Toxicity Not expected to be genotoxic under occupational exposure conditions.

Carcinogenicity No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.

Reproductive Effects Contains components which have been classified as: Possible risk of toxicity in developing human offspring. Possible risk of impaired fertility in humans.

Other Adverse Effects Overexposure in the workplace might have the following effects: symptoms of hypersensitivity (such as skin rash, hives, itching). Assessment based on limited information.

12. ECOLOGICAL INFORMATION

Summary This material contains an active pharmaceutical ingredient that may have reproductive or developmental effects on environmental organisms. Appropriate precautions should be taken to limit release of this material to the environment. Local regulations and procedures should be consulted prior to environmental release.

ECOTOXICITY

Aquatic

Activated Sludge Respiration This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.

IC50: > 1083 mg/l, 3 Hours, Activated sludge, Nominal

Daphnid This material contains an active pharmaceutical ingredient that is not toxic to daphnids.

EC50: > 2.7 mg/l, 48 Hours, Daphnia magna, Static renewal test

NOEC: 2.7 mg/l

MOBILITY

Partitioning

This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient may have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION

Biodegradation

This material contains an active pharmaceutical ingredient that is not readily biodegradable (as defined by 1993 OECD Testing Guidelines).

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Aerobic - Inherent

Percent Degradation: 0 %, 28 days, Modified MITI (II) Test., Activated sludge

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

Regulatory Requirements Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling**Transport Information**

Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)

Classification This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

SDS Version Number 12

SDS Sections Updated**Sections**

HAZARDS IDENTIFICATION

TOXICOLOGY INFORMATION

Subsections

Health

Other Adverse Effects

Sensitisation

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.