

SAFETY DATA SHEET



GlaxoSmithKline

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

Material	ALBENZA TABLETS
Synonyms	ALBENZA 200 MG TABLETS * ESKAZOLE TABLETS 200 MG * ZENTEL TABLETS 200 MG * NDC NO. 0007-5500-40 * ALBENDAZOLE, 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. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
ALBENDAZOLE	54965-21-8	30
NON-HAZARDOUS INGREDIENTS	Unassigned	70

3. HAZARDS IDENTIFICATION

Fire and Explosion	Expected to be non-combustible.
* Health	<p>Exposure might occur via inhalation; ingestion; skin; eyes. May produce adverse effects on the development of human offspring. May impair the quantity or quality of human milk production. Possible effects of overexposure in the workplace include: nausea; vomiting; abdominal pain; headache.</p> <p>Health effects information is based on hazards of components. Handling this product in its final form presents minimal risk from occupational exposure.</p>
Environment	Dangerous for the environment. Very toxic to aquatic organisms.

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.
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 current prescribing information or to the local poison control information centre.
* Medical Conditions Caused or Aggravated by Exposure	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.
* Health Surveillance Procedures	Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.
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

INGREDIENT ALBENDAZOLE

GSK Occupational Hazard Category 3

GSK Occupational Exposure Limit 100 MCG/M3 (8 HR TWA) REPRODUCTIVE HAZARD

Occupational Hygiene Air Monitoring Methods For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

Other Equipment or Procedures None required for normal handling. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form Film-coated tablet.

10. STABILITY AND REACTIVITY

Stability This product is expected to be stable.

Conditions to Avoid None for normal handling of this product.

11. TOXICOLOGICAL INFORMATION

- * Oral Toxicity** Not expected to be toxic following ingestion. Assessment based upon effects of individual components.
Acute: Rat
LD50: > 2000 mg/kg
- Inhalation Toxicity** No studies have been conducted.
- * Skin Effects** Irritation is not expected following direct contact. Assessment based upon effects of individual components.
- * Eye Effects** Irritation is not expected following direct contact with eyes. Assessment based upon effects of individual components.
- Target Organ Effects** No specific target organ effects have been identified.
- * Sensitisation** Sensitisation (allergic skin reaction) is not expected. Assessment based upon effects of individual components.
- * Genetic Toxicity** Not expected to be genotoxic under occupational exposure conditions. Assessment based upon effects of individual components.
- * Carcinogenicity** No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
- * Reproductive Effects** This material contains components which have been classified as: Known or presumed to cause toxicity in developing human offspring. Possible risk of affecting the quantity or the quality of breast milk in humans.
- * Pharmacological Effects** This preparation contains ingredient(s) with the following activity: a microtubule synthesis inhibitor. It is an agent intended for the treatment of parasitic infection. Adverse effects of overexposure might include: nausea; vomiting; headache; abdominal pain.

* Other Adverse Effects None known for this material in humans.

12. ECOLOGICAL INFORMATION

Summary This material contains an active pharmaceutical ingredient that has been tested, and which may be very toxic to aquatic organisms if released directly to the environment. Consult the MSDS of the active ingredient for specific information about potential environmental effects. Appropriate precautions should be taken to limit release of this mixture to the environment. Local regulations and procedures should be consulted prior to environmental release.

Specific information on the active pharmaceutical ingredient is provided below.

ECOTOXICITY

Aquatic

Activated Sludge Respiration No toxicity to sludge microorganisms was observed for the active pharmaceutical ingredient in this mixture, but the upper range of the test was limited by the low water solubility of the compound.

IC50: > 0.27 mg/L, 3 Hours, Residential sludge

Microtox Microtox is a general toxicity test which utilizes a sensitive marine photo bacteria as the test species. This material contains an active pharmaceutical ingredient that is toxic to these microorganisms.

EC50: 0.36 mg/L, 15 Minutes

Algal No toxicity to algae was observed for the active pharmaceutical ingredient in this mixture, but the upper range of the test was limited by the low water solubility of the compound.

IC50: > 50 mg/L, 72 Hours, Selenastrum capricornutum, green algae

Daphnid This material contains an active pharmaceutical ingredient that is very toxic to daphnids.

EC50: 0.024 mg/L, 48 Hours, Daphnia magna, Static test

NOEL: 0.017 mg/L, 48 Hours, Daphnia magna, Static test

Terrestrial

Earthworm This mixture contains an active pharmaceutical ingredient that is not toxic to earthworms.

Lumbricus rubellus, redworm

EC50: 15 mg/kg, 60 Days, agricultural soil

MOBILITY

Solubility This material contains an active pharmaceutical ingredient that for environmental fate predictions has very low solubility in water.

Adsorption This material contains an active pharmaceutical ingredient that is likely to adsorb to soil or sediment. It may persist in soil or sediment if released directly to the environment.

Soil Sediment Sorption (log Koc): 3.89 to 4.44, Measured

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 will not have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION

Photolysis

This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water when exposed to light. Aqueous photolysis may be a significant depletion mechanism.

Half-Life, Aqueous: 0.1 to 1.65 Days, Measured

UV/Visible Spectrum: 295 nm at pH 7

BIOACCUMULATION

This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.

Bioconcentration Factor: 1.16 Measured, Lepomis macrochirus, bluegill sunfish

13. DISPOSAL CONSIDERATIONS

Disposal

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.

Recommendations**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

Date Approved/Revised 26-Jun-2007

SDS Version Number 12

SDS Sections Updated**Sections**

FIRST-AID MEASURES

Subsections

Antidotes
Eye Contact
Health Surveillance Procedures
Ingestion
Inhalation

SDS Sections Updated**Sections**

FIRST-AID MEASURES

HAZARDS IDENTIFICATION

TOXICOLOGY INFORMATION

SubsectionsMedical Conditions Caused or Aggravated by
Exposure

Medical Treatment

Skin Contact

Health

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.