

SAFETY DATA SHEET



GlaxoSmithKline

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

Material	DYAZIDE CAPSULES
Synonym(s)	DYAZIDE CAPSULES 25 MG/37.5 MG * TRIAMTERENE AND HYDROCHLOROTHIAZIDE, 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 #	Percent	EC-No.
HYDROCHLOROTHIAZIDE	58-93-5	16	
TRIAMTERENE	396-01-0	24	206-904-3
Other components below reportable levels		60	

3. HAZARDS IDENTIFICATION

Fire and Explosion	Expected to be non-combustible.
Health	<p>Caution - Pharmaceutical agent. Eye irritant. Exposure might occur via ingestion; skin; eyes. Health effects information is based on hazards of components.</p>
Environment	No information is available about the potential of this product to produce adverse environmental effects.

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.

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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 Medical treatment in cases of overexposure should be treated as an overdose of a thiazide diuretic. 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 None for occupational exposure.

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 or foam extinguishers are recommended. Carbon dioxide or dry powder 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 capsules.

STORAGE

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

INGREDIENT	TRIAMTERENE
GSK Occupational Hazard Category	1
GSK Occupational Exposure Limit	1000 MCG/M3 (8 HR TWA)
INGREDIENT	HYDROCHLOROTHIAZIDE
GSK Occupational Hazard Category	2
GSK Occupational Exposure Limit	500 MCG/M3 (8 HR TWA)

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection	Wear approved safety glasses with side shields if eye contact is possible.
Other Equipment or Procedures	Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Clarity	Opaque.
Colour	Red/white.
Physical Form	Capsule.

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 product contains active ingredient(s) with the following activity: diuretic that can affect the function of the kidneys.
Target Organ Effects	No specific target organ effects have been identified.
Routes of Exposure	
Oral Toxicity	Adverse effects might occur following ingestion.
Inhalation Toxicity	No studies have been conducted.
Skin Effects	Irritation is not expected following direct contact.
Eye Effects	Irritation might occur following direct contact with eyes.
Sensitisation	Sensitisation (allergic skin reaction) is not expected.
Genetic Toxicity	Not expected to be genotoxic under occupational exposure conditions.
Carcinogenicity	Contains a material classified as a carcinogen by external agencies. (NTP) Not expected to produce cancer in humans under occupational exposure conditions.
Reproductive Effects	Not expected to produce adverse effects on fertility or development under occupational exposure conditions. Insufficient information available to classify this material for hazard to milk production.
Other Adverse Effects	None known for occupational exposure.

12. ECOLOGICAL INFORMATION

Summary	This material contains two or more active pharmaceutical ingredients that have been tested, one of which may be harmful if released directly to the environment. Specific information on that active pharmaceutical ingredient is provided below. 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.
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ECOTOXICITY**Aquatic****Activated Sludge
Respiration**

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

IC50: > 100 mg/l, 3 Hours, Activated sludge, Nominal

NOEC: 100 mg/l, 3 Hours, Activated sludge, Static test

Algal

This material contains an active pharmaceutical ingredient that is harmful to algae.

IC50: 14 mg/l, 72 Hours, Selenastrum capricornutum, green algae, Measured

NOEC: 5 mg/l, 72 Hours, Selenastrum capricornutum, green algae, Static test

Daphnid

No toxicity to daphnids 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 this compound. This material contains an active pharmaceutical ingredient that is not harmful to daphnids in chronic toxicity studies.

EC50: > 10 mg/l, 48 Hours, Daphnia magna, Measured

NOEC: 10 mg/l, 48 Hours, Daphnia magna, Static test

Chronic LOEC: > 10 mg/l, 7 Days, Ceriodaphnia dubia, Nominal

Chronic NOEC: 10 mg/l

Fish

No toxicity to fish was observed for the active pharmaceutical ingredient, but the upper range of the test was limited by the low water solubility of the compound.

Adult Oncorhynchus mykiss, rainbow trout

EC50: > 13 mg/l, 96 Hours, Measured

Adult Oncorhynchus mykiss, rainbow trout

NOEC: 13 mg/l, 96 Hours, Static test

MOBILITY**Solubility**

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

Volatility

This material contains an active pharmaceutical ingredient that will not readily enter into air from water.

Henry's Law Constant < 1.90E-15 atm m³/mol, Estimated at 25 C

Adsorption

This material contains an active pharmaceutical ingredient that is not likely to adsorb to soil or sediment if released directly to the environment. This material contains an active pharmaceutical ingredient that is not likely to adsorb to sludge or biomass if released directly to the environment.

Sludge Biomass 1.95 Measured at pH 7

Distribution Coefficient
(log K_d):

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 is likely to undergo photodegradation.

UV/Visible Spectrum: 356 nm, Measured

Biodegradation

This material contains an active pharmaceutical ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment.

Aerobic - Inherent

Percent Degradation: 50 %, 14 days, Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

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Bioaccumulation

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

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

14

SDS Sections Updated**Sections**

COMPOSITION / INFORMATION ON INGREDIENTS

Subsections

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.