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

Material: DYAZIDE CAPSULES, REFORMULATED

Company Name: GlaxoSmithKline, Environment Health & Safety
2200 Renaissance Blvd. Suite 105
King of Prussia, PA 19406 USA

General Information +1 610-239-5229
24-Hour Medical Emergency +1-800-228-5635, Ext. 221
Outside North America +1-612-221-3999, Ext. 221
24-Hour Transport Emergency +1-800-424-9300
Outside North America +1-703-527-3887

2 COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS RN</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>NON-HAZARDOUS INGREDIENTS</td>
<td>Unassigned</td>
<td>1</td>
</tr>
<tr>
<td>TRIAMTERENE</td>
<td>396-01-0</td>
<td>24</td>
</tr>
<tr>
<td>GLYCINE</td>
<td>56-40-6</td>
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</tr>
<tr>
<td>HYDROCHLOROTHIAZIDE</td>
<td>58-93-5</td>
<td>16</td>
</tr>
<tr>
<td>LACTOSE</td>
<td>63-42-3</td>
<td>30</td>
</tr>
<tr>
<td>POLYVINYLPYRROLIDONE</td>
<td>9003-39-8</td>
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</tr>
<tr>
<td>MICROCRYSTALLINE CELLULOSE</td>
<td>Unassigned</td>
<td>7</td>
</tr>
<tr>
<td>SODIUM STARCH GLYCOLATE</td>
<td>9063-38-1</td>
<td>9</td>
</tr>
</tbody>
</table>

3 HAZARDS IDENTIFICATION

HEALTH HAZARDS

Skin Contact: Allergic reaction and irritation are not expected following direct contact.
Eye Contact: Irritation with redness, swelling, or blurred vision can occur following direct contact with broken capsules.
Inhalation: Not expected to occur during normal handling of this product.
Ingestion: Effects after ingestion might include headache, dryness of mouth, increased thirst, weak or irregular pulse, mood changes, muscle cramps, pain, nausea, vomiting, weakness, fatigue or other signs of electrolyte imbalance.
Conditions Aggravated by Exposure: Diabetics or individuals taking medications for kidney or cardiovascular disorders might be sensitive to effects of this material following overexposure.

ENVIRONMENTAL HAZARDS

Summary: No information is available about the potential of this material to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.
4 FIRST-AID MEASURES

Skin Contact
In the event of occupational skin contact, wash contaminated area thoroughly.

Eye Contact
Flush eyes continuously with water for at least 15 minutes. Do not use a chemical neutraliser. Obtain medical assistance if symptoms occur.

Inhalation
Not applicable for this product.

Ingestion
In the event of occupational ingestion, seek medical advice. Induction of vomiting is not a recommended first-aid procedure.

Notes to Physician
Medical treatment in cases of overexposure should be treated as an overdosage of thiazide diuretic. Refer to current prescribing information or to local poison control information centers.

Antidotes
No specific antidotes known.

5 FIRE-FIGHTING MEASURES

Fire and Explosion Hazards
Not expected for the product, although the packaging is combustible.

Fire Control
This material is non-combustible. Water is recommended for fires involving packaging.

Special Firefighting Procedures
No special firefighting requirements. Where appropriate, collect product or firefighting water for later disposal.

6 ACCIDENTAL RELEASE MEASURES

Spills
No special requirements for spills from single containers. For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems. Use protective clothing during clean-up prior to disposal of spilled material.

Decontamination Procedures
Water can be used for clean-up and decontamination operations. No specific decontamination or detoxification procedures have been identified for this substance.

7 HANDLING AND STORAGE

Handling
Avoid breaking or crushing capsules.

Storage
Store at room temperature (15 to 30 degrees C; 59 to 86 degrees F).

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

TRIAMTERENE

SB Hazard Category 1
SB Personal Exposure Limit 1000 MCG/M3 8 HR TWA
Allowable Daily Limit 10 mg/day

HYDROCHLOROTHIAZIDE

SB Hazard Category 1
SB Personal Exposure Limit 500 MCG/M3 8 HR TWA
Allowable Daily Limit 5 mg/day
Occupational Hygiene Method PS-S4B.-S&AM-1114

PERSONAL PROTECTIVE EQUIPMENT

Other Equipment or Procedures Wash hands and arms thoroughly after handling. None required for normal handling.
9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance
- Clarity: Opaque.
- Colour: Red/white.
- Physical Form: Capsule.

Solubility (Water) Most components are soluble in water.

10 STABILITY AND REACTIVITY

Conditions to Avoid None for normal handling of this material.

11 TOXICOLOGICAL INFORMATION

 Oral Toxicity The oral LD50 is expected to be less than 2000 mg/kg in rats, based on calculations relating to the effects of individual components and concentrations present.

 Inhalation Toxicity Not applicable for this product.

 Skin Toxicity Irritation is not expected based on effects of individual components.

 Eye Effects Irritation might occur based on effects of individual components.

 Sensitisation Sensitisation (allergic skin reaction) is not expected, based on effects of individual components.

 Genetic Toxicity Not expected to be genotoxic, based on effects of individual components.

 Carcinogenicity Not expected to produce cancer in humans under occupational exposure conditions (Carcinogen Alert Level 3). Positive results occurred in some studies that are not considered to be relevant to occupational exposure conditions.

 Contains a material classified as a carcinogen by external agencies; NTP

 Reproductive Effects This product is recommended for use by pregnant women only if clearly needed and is assigned to Category C in current prescribing information.

 Other Toxicological or Adverse Effects None known for this material in humans.

12 ECOLOGICAL INFORMATION

Summary No information is available about the potential of this material to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.

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.

SB Standards and Guidance SB E-7 and G-E-7.

Regulatory Requirements Consult local regulations prior to disposal.

14 TRANSPORT INFORMATION

The MSDS should accompany all shipments for reference in the event of spillage or accidental release.

Classification and Labelling Transportation and shipping of this material as packaged is not restricted for air, maritime, US ground and European ground transport purposes.<n>

15 REGULATORY INFORMATION

European Union No European Union labelling requirements.

Classification and Labelling

16 OTHER INFORMATION
This product is exempt from hazard labelling requirements since it is regulated either as a medicine or cosmetic product.

**References**

 SB HAZARD DETERMINATION

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**Date Approved/Revised** 08-Jan-2001  
**Version Number** 8

**MSDS Sections Updated**

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<th>Sections</th>
<th>Subsections</th>
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<tr>
<td>EXPOSURE CONTROLS / PERSONAL PROTECTION</td>
<td>Other Equipment or Procedures</td>
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