SAFETY DATA SHEET

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

Material: EXTINA FOAM

Synonym(s): EXTINA (KETOCONAZOLE) FOAM, 2% * KETOCONAZOLE FOAM 2% * FORMULATION CODE: R0125 * STIEFEL PRODUCT * KETOCONAZOLE, FORMULATED PRODUCT

Recommended Use: Cosmetic Product

Note: 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.

Company Name

Stievel Laboratories, Inc. (a GSK company)
GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS  UK
UK General Information (normal business hours):  +44-20-8047-5000

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 (by country / geographic region):
Africa / EU / Israel / Middle East (English / European languages):            +44 (0) 1235 239 670
Asia Pacific (except China):                                                                                  +65 3158 1074
China:                                                                                                               +86 10 5100 3039
Middle East / Africa (Arabic-speaking countries):                                       +44 (0) 1235 239 671
US:                                                                                                                     +1 703 527 3887
available 24 hrs/7 days; multi-language response

MEDICAL EMERGENCIES:                                                                 +1 612 221 3999, Ext 221
available 24 hrs/7 days; multi-language response

2. HAZARDS IDENTIFICATION

Fire and Explosion Hazards

This product is extremely flammable.

Health

Caution - Pharmaceutical agent.
Caution - The toxicological properties of this material have not been fully investigated.
Not expected to be a significant health hazard unless product is spilt.
Health effects information is based on hazards of components.
Contains ingredient(s) that: May produce adverse effects on the development of human offspring.
May produce adverse effects on human fertility.
Possible effects of overexposure in the workplace include: irritation; headache; symptoms similar to alcohol intoxication; symptoms of hypersensitivity (such as skin rash, hives, itching).
Exposure might occur via inhalation; ingestion; skin; eyes.
Environment

No information is available about the potential of this product to produce adverse environmental effects. This product contains an ingredient(s) that is very toxic to aquatic organisms; and may cause long-term adverse effects in the aquatic environment.

* 3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS #</th>
<th>Percent</th>
<th>EC-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETHANOL</td>
<td>64-17-5</td>
<td>55.0 - 58.0</td>
<td>200-578-6</td>
</tr>
<tr>
<td>ISOBUTANE</td>
<td>75-28-5</td>
<td>0.4 - 2.2</td>
<td>200-857-2</td>
</tr>
<tr>
<td>KETOCONAZOLE</td>
<td>65277-42-1</td>
<td>2.0</td>
<td>265-667-4</td>
</tr>
<tr>
<td>N-BUTANE</td>
<td>106-97-8</td>
<td>0.1 - 1.0</td>
<td>203-448-7</td>
</tr>
<tr>
<td>PROPANE</td>
<td>74-98-6</td>
<td>0.2 - 1.4</td>
<td>200-827-9</td>
</tr>
</tbody>
</table>

Other components below reportable levels 35.0 - 43.0

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

Using appropriate personal protective equipment, move exposed subject to fresh air. If breathing is difficult or ceases, ensure and maintain ventilation. Give oxygen as appropriate. The exposed subject should be kept warm and at rest. Obtain medical attention in cases of known or possible over exposure, or with symptoms including chest pain, difficulty breathing, loss of consciousness or other adverse effects, which may be delayed.

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

In allergic individuals, exposure to this material may require treatment for initial or delayed allergic symptoms and signs. This may include immediate and/or delayed treatment of anaphylactic reactions.

Medical Conditions Caused or Aggravated by Exposure

Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.

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. Exposed individuals are encouraged to report symptoms of skin and respiratory irritation to an occupational health professional or line management. These symptoms may include, but are not limited to, skin conditions, bronchitis, asthma, or nasal irritation.

Antidotes

No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards

This product is extremely flammable. Aerosol containers may violently rupture when exposed to the heat of fire.

Extinguishing Media

Water is recommended for fires involving packaging.
6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions**
- Stop leak and eliminate all sources of ignition (no smoking, sparks or flames). Fence or cordon the affected area and do not allow individuals to touch or walk through the spilled material unless wearing appropriate protective clothing. Wear protective clothing and equipment consistent with the degree of hazard. Vapour-suppressing foam or water spray may be used to control vapours as appropriate.

**Environmental Precautions**
- Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.

**Clean-up Methods**
- Spread an inert absorbent on the spill and place in a suitable, properly labelled container for recovery or disposal. Equipment used for clean-up should be earthed (grounded) and non-sparking.

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

7. HANDLING AND STORAGE

**HANDLING**
- **General Requirements** Handle in open or well ventilated areas.
- **Ignition Controls** Keep this material away from all forms of ignition such as open flames, mechanical sparks, frictional heat and hot surfaces.

**STORAGE**
- Keep material in sealed containers in a cool, well-ventilated area away from sources of ignition.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**OCCUPATIONAL EXPOSURE LIMITS**

<table>
<thead>
<tr>
<th>INGREDIENT</th>
<th>KETOCONAZOLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>GSK Occupational Hazard Category</td>
<td>2</td>
</tr>
<tr>
<td>GSK Occupational Exposure Limit</td>
<td>200 mcg/m³ (8 HR TWA)</td>
</tr>
</tbody>
</table>

**Other Exposure Limits**
- Regulatory or other health protective exposure control standards have been developed for a component, or components, in this mixture. Consult supplier SDS, company occupational hygienist, or safety department.

**ENGINEERING CONTROLS**
- **Administrative** 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.

**PERSONAL PROTECTIVE EQUIPMENT**
- **Eye Protection** Wear approved safety glasses with side shields if eye contact is possible.
- **Other Equipment or Procedures** An eye wash station should be available. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**
- Colour: White.
- Physical Form: Foam.
- Packaging: Aerosol container.
10. STABILITY AND REACTIVITY

Conditions to Avoid
Pressurised container. Protect from sunlight and do not expose to temperatures exceeding 50 degrees C. Do not puncture or incinerate when empty. Do not overheat containers, they might violently rupture.

11. TOXICOLOGY INFORMATION

Pharmacological Effects
This product contains active ingredient(s) with the following activity: an antifungal agent.

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

Symptoms of Overexposure
Possible effects of overexposure in the workplace include: irritation; headache; symptoms similar to alcohol intoxication; symptoms of hypersensitivity (such as skin rash, hives, itching).

Routes of Exposure

Oral Toxicity
Adverse effects might occur following ingestion. Assessment based upon effects of individual components.

Inhalation Toxicity
No studies have been conducted. Overexposure may result in irritation of the respiratory tract.

Skin Effects
Minor irritation might occur following direct contact.

Eye Effects
Irritation might occur following direct contact with eyes. May cause reddening, swelling and pain. Assessment based upon effects of individual components.

Sensitisation
Allergic skin reactions might occur following repeated contact with this material in susceptible individuals. Symptoms of hypersensitivity may include skin rash, hives and itching.

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

Carcinogenicity
Contains a material (ethanol) classified as a carcinogen by external agencies. (IARC) High concentrations or doses administered over an extended period of time were required to produce adverse effects.

Reproductive Effects
The ingredient ketoconazole has caused adverse effects to fertility in humans. The ingredient ketoconazole has caused adverse effects on the development of unborn offspring in animal studies. The ingredient ethanol has caused adverse effects on the development of unborn offspring in humans. Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

Other Adverse Effects
Overexposure might lead to increased sensitivity of the skin to ultraviolet radiation and sunlight.

12. ECOLOGICAL INFORMATION

Summary
No information is available about the potential of this product to produce adverse environmental effects. This material contains an active ingredient (Ketoconazole) 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 material to the environment. 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.

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

Proper Shipping Name: Aerosols
(KETOCONAZOLE FOAM 2% (CONTAINING ETHANOL))

UN Number: UN 1950
Class/Division: 2.1
Packing Group: Not applicable
Risk Label(s): Class 2.1 Flammable Gas

International Air Transport (IATA Requirements)

UN/ID Number: ID 8000
Proper Shipping Name/Description: Consumer Commodity
ICAO/IATA Class/Division: 9
Classification and Labelling: See IATA Special Provision A98.
Packing Instructions: See Packing Instruction Y963.
Limited Quantities: May be able to ship as an Excepted or Limited Quantity.

International Maritime Transport (IMDG Requirements)

Classification and Labelling: As UN Classification and Labelling above
Limited Quantities: May be able to ship as an Excepted or Limited Quantity.

US Domestic Transport (DOT Requirements)

Proper Shipping Name: Consumer Commodity, ORM-D
DOT Hazard Class/Division: ORM-D
UN/NA Number: None
Classification and Labelling: See 173.306(i); After 1Oct08, see 173.306(j).
Limited Quantities: May be able to ship as an Excepted or Limited Quantity.

European Ground Transport (ADR/RID Requirements)

Classification and Labelling: Not subject to ADR, see SP 601.

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.


Classification: This product 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: 1
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.