

SAFETY DATA SHEET



GlaxoSmithKline

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

Material	PHAZYME ULTRA STRENGTH SOFTGELS 180 MG	
Synonyms	PHAZYME ULTRA STRENGTH SOFTGELS 180MG (US AND CANADA) * PHAZYME GELULES MOLLES 180MG * FORMULA NO. IB1644 * SIMETHICONE, FORMULATED PRODUCT	
Company Name	GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK	
	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
	GlaxoSmithKline, Corporate Environment, Health & Safety 2200 Renaissance Blvd, Suite 105 King of Prussia, PA 19406 US	
	US General Information:	+1-888-825-5249
	Transport Emergency (non EU)	+1-703-527-3887
		US number, available 24 hours Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
SIMETHICONE	8050-81-5	68
NON-HAZARDOUS INGREDIENTS	Unassigned	32

3. HAZARDS IDENTIFICATION

Fire and Explosion	Expected to be non-combustible.
Health	Handling this product in its final form presents minimal risk from occupational exposure. Health effects information is based on hazards of components.
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.
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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	None.
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 or foam extinguishers are recommended.
* 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 are considered necessary for the control of fire and explosion hazards.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

Physical Form	Capsule.
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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.
Skin Effects	Irritation is not expected following direct contact.
Eye Effects	Irritation is not expected 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	Not expected to produce cancer in humans under occupational exposure conditions. No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
Reproductive Effects	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
* Other Adverse Effects	None known for occupational exposure.

12. ECOLOGICAL INFORMATION

Summary	No information is available about the potential of this product to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.
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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.
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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	Exempt when packaged for sale to consumers in a retail establishment.
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Other US Regulations

TSCA Status	Exempt
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16. OTHER INFORMATION

References	GSK Hazard Determination
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Date Approved/Revised 25-May-2005

SDS Version Number 6

SDS Sections Updated**Sections**

ACCIDENTAL RELEASE MEASURES

DISPOSAL CONSIDERATIONS

ECOLOGICAL INFORMATION

EXPOSURE CONTROLS / PERSONAL PROTECTION

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Decontamination Procedures

Environmental Precautions

Personal Precautions

Spills

Disposal Recommendations

GSK Standards and Guidance

Regulatory Requirements

Activated Sludge Respiration

Adsorption

Algal

Algal Degradation

Bioaccumulation

Biodegradation

Daphnid

Distribution

Earthworm

Ecotoxicity

Fish

Hydrolysis

Microbial Growth Inhibition

Microtox

Mobility

Other Adverse Effects

Other Species - Aquatic

Other Species - Terrestrial

Partitioning

Persistence/Degradation

Photolysis

Solubility

Summary

Volatility

Administrative

Containment

Exposure Controls

Eye Protection

Gloves

Occupational Hygiene Air Monitoring Methods

Occupational Hygiene Surface Monitoring Metho

Other Equipment or Procedures

Other Exposure Limits

Other Information

Other Protective Equipment

Respirators

Surface Exposure Target

SDS Sections Updated**Sections**

EXPOSURE CONTROLS / PERSONAL PROTECTION

FIRE-FIGHTING MEASURES

FIRST-AID MEASURES

HANDLING AND STORAGE

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Inhalation

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Health

Ingestion

Inhalation

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Skin Contact

Summary

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Disclaimer Safety Summary

Disclaimer Technical Sheet

Information on Hazard Label

Nature of/Reason for Amendment

Other Information

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SB Classification

Target Organ

European Union Classification and Labelling
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Summary

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STABILITY AND REACTIVITY

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US OSHA Standard (29 CFR Part 1910.1200) -
ClassificationUS OSHA Standard (29 CFR Part 1910.1200) -
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Hazardous Decomposition Products

Hazardous Polymerisation

Materials to Avoid

Stability

Thermal Stability

Carcinogenicity

Eye Effects

Genetic Toxicity

Inhalation Toxicity

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Class/Division

Emergency Action Code

Emergency Response Guide Number

EMS Number

European Ground Transport

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Hazard Identification Number

Item

Marginal

Marine Pollutant

MFAG Number

NA Number

Packing Group

Packing Instructions

Proper Shipping Name

Reportable Quantity (RQ)

Special Precautions for Transport

Subsidiary Risk

Summary

Technical Name

Transport Category

Transport Classification and Labelling

Transport Label(s)

Tremcard Number

UN Number

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.