

SAFETY DATA SHEET



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

Material ALLI

Synonym(s) ORLISTAT 60 MG CAPSULES * ORLISTAT OTC CAPSULES * PROJECT GEMINI * GEMINI ROW * ORLISTAT, 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
One Franklin Plaza, 200 N 16th Street
Philadelphia, PA 19102-1225 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. HAZARDS IDENTIFICATION

Fire and Explosion Hazards

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

Dangerous for the environment. Toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
ORLISTAT	96829-58-2	49.95	
Other components below reportable levels		50.05	

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 local poison control information centre.
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 is recommended for fires involving packaging.
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 or corrosive thermal decomposition products are expected when this material 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

OCCUPATIONAL EXPOSURE LIMITS

INGREDIENT	ORLISTAT
GSK Occupational Hazard Category	1
GSK Occupational Exposure Limit	2000 mcg/m3 (8 HR TWA)

ENGINEERING CONTROLS

Containment	No special engineering controls are required.
Other Equipment or Procedures	Wash hands and arms thoroughly after handling.

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. TOXICOLOGY INFORMATION

Target Organ Effects	No specific target organ effects have been identified.
Routes of Exposure	
Oral Toxicity	Not expected to be toxic following ingestion.
Inhalation Toxicity	No studies have been conducted.
Skin Effects	Irritation is not expected following direct contact.
Eye Effects	Irritation is not expected following direct contact with eyes.
Sensitisation	Potential for inducing allergic reactions via the dermal or respiratory route is not known.
Genetic Toxicity	Not expected to be genotoxic under occupational exposure conditions.
Carcinogenicity	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

This material contains an active pharmaceutical ingredient that has been tested, and which may be toxic to aquatic organisms if released directly to the environment. This material contains an active pharmaceutical ingredient that may persist in 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.

Specific information on the active pharmaceutical ingredient is provided below.

ECOTOXICITY

Aquatic

Activated Sludge Respiration

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

NOEC: 50 mg/l, 3 Hours, Activated sludge

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: > 1.92 mg/l, 10 Days, Selenastrum capricornutum, green algae

NOEC: 1.92 mg/l, 10 Days, Selenastrum capricornutum, green algae

Daphnid

This material contains an active pharmaceutical ingredient that is toxic to daphnids. This material contains an active pharmaceutical ingredient that is very toxic to daphnids in chronic toxicity studies.

EC50: 6.92 mg/l, 48 Hours, Daphnia magna

NOEC: 1.95 mg/l, 48 Hours, Daphnia magna

Chronic EC50: 0.15 mg/l, 21 Days, Daphnia magna, Static renewal test

Chronic LOEC: 0.0065 mg/l, 21 Days, Daphnia magna

Chronic NOEC: 0.0016 mg/l, 21 Days, Daphnia magna

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: > 18.5 mg/l, 96 Hours

Adult Oncorhynchus mykiss, rainbow trout

NOEC: 18.5 mg/l, 96 Hours

Terrestrial

Earthworm

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

EC50: 907 mg/kg, 28 Days, Lumbricus terrestris, earthworm,

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. The active pharmaceutical ingredient may persist in soil or sediment if this mixture is released directly to the environment.

Soil Sediment Sorption (log Koc): 5.2, 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 may have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION

Biodegradation

This material contains an active pharmaceutical ingredient that is not readily biodegradable (as defined by 1993 OECD Testing Guidelines). It may persist in the environment.

Aerobic - Ready

Percent Degradation: 18 %, 30 days

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 material.

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

Exempt when packaged for sale to consumers in a retail establishment.

Other US Regulations

TSCA Status

Exempt

16. OTHER INFORMATION

References

GSK Hazard Determination

SDS Version Number

5

SDS Sections Updated

Sections

IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY

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.