

Safety Data Sheet

acc. to OSHA HCS

Page 1/8

Printing date 07/10/2017
Reviewed on 07/10/2017

- **1.1 Product identifier**
- **Trade name: Orlistatum**
Orlistat
- **Product Code:** 105602
- **CAS Number:**
96829-58-2
- **Application of the substance / the mixture** Additive for cosmetic or pharmaceutical preparations
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Fagron Inc
2400 Pilot Knob Road
St. Paul, MN 55120
www.fagron.us
QA@fagron.us
- **Information department:**
Tel.: 800-423-6967
Fax: 800-339-1596
- **1.4 Emergency telephone number:**
Emergency Telephone:
US: 1-800-535-5053
International: 1-352-323-3500

2 Hazard(s) identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS06 Skull and crossbones

Acute Tox. 3 H311 Toxic in contact with skin.



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

STOT SE 3 H335 May cause respiratory irritation.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** The substance is classified and labeled according to the CLP regulation.
- **Hazard pictograms** GHS06, GHS07
- **Signal word** Danger
- **Hazard statements**
H311 Toxic in contact with skin.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
- **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapors/spray

(Contd. on page 2)

USA



Trade name: Orlistatum
Orlistat

(Contd. of page 1)

- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P321 Specific treatment (see on this label).
- P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Classification system:**
- **NFPA ratings (scale 0 - 4)**
- **HMS-ratings (scale 0 - 4)**
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **3.1 Chemical characterization: Substances**
- **CAS No. Description**
96829-58-2 Orlistatum
Orlistat
- **Identification number(s) -**

4 First-aid measures

- **4.1 Description of first aid measures**
- **General information:**
Immediately remove any clothing soiled by the product.
In case of irregular breathing or respiratory arrest provide artificial respiration.
- **After inhalation:** In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** Rinse out mouth and then drink plenty of water.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

USA

(Contd. on page 3)



Trade name: Orlistatum
Orlistat

(Contd. of page 2)

6 Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
- **Protective Action Criteria for Chemicals**
- **PAC-1:** Substance is not listed.
- **PAC-2:** Substance is not listed.
- **PAC-3:** Substance is not listed.

7 Handling and storage

- **7.1 Precautions for safe handling**
Thorough dedusting.
Ensure good ventilation/exhaustion at the workplace.
- **Information about protection against explosions and fires:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Store in cool, dry conditions in well sealed receptacles.
- **7.3 Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **8.1 Control parameters**
- **Components with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Store protective clothing separately.
Avoid contact with the eyes and skin.

(Contd. on page 4)

USA

Trade name: Orlistatum
Orlistat

(Contd. of page 3)

· **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles

9 Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Powder

Color: White

· **Odor:** Characteristic

· **Odor threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Product is not flammable.

· **Ignition temperature:**

Decomposition temperature: Not determined.

· **Auto igniting:** Not determined.

(Contd. on page 5)

USA

Safety Data Sheet

acc. to OSHA HCS

Trade name: Orlistatum
Orlistat

(Contd. of page 4)

- **Danger of explosion:** Product does not present an explosion hazard.
- **Explosion limits:**
 - Lower: Not determined.
 - Upper: Not determined.
- **Vapor pressure:** Not applicable.
- **Density:** Not determined.
- **Relative density:** Not determined.
- **Vapor density:** Not applicable.
- **Evaporation rate:** Not applicable.
- **Solubility in / Miscibility with Water:** Not determined.
- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
 - Dynamic: Not applicable.
 - Kinematic: Not applicable.
- **9.2 Other information** No further relevant information available.

10 Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:**
Toxic in contact with skin.

LD/LC50 values that are relevant for classification:

Oral	LD50	>5000 mg/kg (Mouse)
		>5000 mg/kg (Rat)
	LD50 (parenteral)	>100 mg/kg (Mouse)
		>100 mg/kg (Rat)

- **Primary irritant effect:**
- **on the skin:**
Causes skin irritation.

(Contd. on page 6)

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Trade name: Orlistatum
Orlistat

(Contd. of page 5)

- **on the eye:**
Causes serious eye irritation.
- **Sensitization:** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **Carcinogenic categories**
- **IARC (International Agency for Research on Cancer)** Substance is not listed.
- **NTP (National Toxicology Program)** Substance is not listed.
- **OSHA-Ca (Occupational Safety & Health Administration)** Substance is not listed.

12 Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 3 (Self-assessment): extremely hazardous for water
Do not allow product to reach ground water, water course or sewage system, even in small quantities.
Danger to drinking water if even extremely small quantities leak into the ground.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

13 Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation:** Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|---------------------------------------|---|
| · 14.1 UN-Number | |
| · DOT, ADR, IMDG, IATA | UN3077 |
| · 14.2 UN proper shipping name | |
| · DOT | Environmentally hazardous substances, solid, n.o.s.
(Orlistatum
Orlistat) |

(Contd. on page 7)

USA

Safety Data Sheet

acc. to OSHA HCS

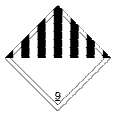
Trade name: Orlistatum
Orlistat

(Contd. of page 6)

· **ADR** 3077 Environmentally hazardous substances, solid, n.o.s. (Orlistatum Orlistat)
 · **IMDG, IATA** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Orlistatum Orlistat)

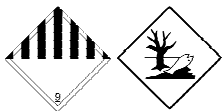
· **14.3 Transport hazard class(es)**

· **DOT**



· **Class** 9 Miscellaneous dangerous substances and articles
 · **Label** 9

· **ADR, IATA**



· **Class** 9 Miscellaneous dangerous substances and articles

· **IMDG**



· **Class** 9 Miscellaneous dangerous substances and articles

· **14.4 Packing group**

· **DOT, ADR, IMDG, IATA** III

· **14.5 Environmental hazards:**

· **Marine pollutant:** No
 · **Special marking (ADR):** Symbol (fish and tree)
 · **Special marking (IATA):** Symbol (fish and tree)

· **14.6 Special precautions for user**

· **Danger code (Kemler):** 90
 · **EMS Number:** F-A,S-F
 · **Stowage Category:** A
 · **Stowage Code:** SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.

(Contd. on page 8)

Trade name: Orlistatum
Orlistat

(Contd. of page 7)

- | | |
|---|---|
| · 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCES, SOLID, N.O.S. (ORLISTATUM ORLISTAT), 9, III |

15 Regulatory information

- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered to be dependable and is accurate to the best of the Company's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. The Company cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

- **Department issuing SDS:**

Fagron US

Quality Assurance

- **Contact:** QA@fagron.us

- **Date of preparation / last revision** 07/10/2017 / 5

- **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Acute Tox. 3: Acute toxicity – Category 3

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

- *** Data compared to the previous version altered.**

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