



# ORLISTAT

## MATERIAL SAFETY DATA SHEET

### 2 Composition, Information on Ingredients

#### 2.1 Chemical name and:

*N*-Formyl-L-leucine(1S)-1-[[[(2S,3S)-3-hexyl-4-oxo-2-oxetanyl]methyl]dodecyl ester; *N*-formyl-L-leucine ester with (3S,4S)-3-hexyl-4-[[[(2S)-2-hydroxytridecyl]-2-oxetanone;

Synonyms Tetrahydrolipstatin

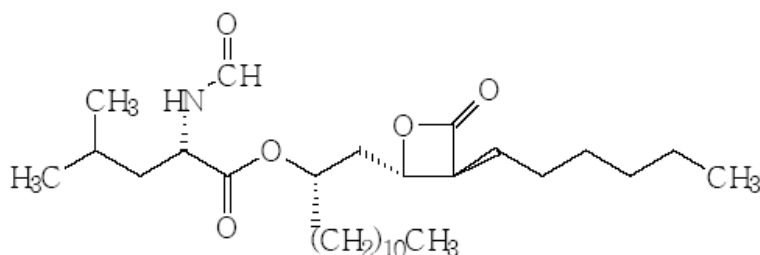
#### 2.2 Composition:

C<sub>29</sub>H<sub>53</sub>NO<sub>5</sub> mol weight: 495.73

C 70.26%, H 10.78%, N 2.83%, O 16.14%

CAS No.: 96829-58-2

#### 2.3 Structure:



### 3 Hazards Identification

#### 3.1 Most important hazards :



#### Hazard statements:

Toxic to aquatic life with long lasting effects. (H411)

#### Precautionary statements:

Avoid release to the environment. (P273)

Collect spillage. (P391)

Dispose of contents/container to ... . (P501)

#### Risk phrases:

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. (R51/53)

#### Safety phrases:

Avoid release to the environment. Refer to special instructions/safety data sheets. (S61)

## **4 First-Aid Measures**

### **4.1 Eye contact**

Rinse immediately with tap water for 10 minutes - open eyelids forcibly

Consult physician

### **4.2 Skin contact**

Remove immediately contaminated clothes, wash affected skin with water and soap

- do not use any solvents

Consult physician

### **4.3 Inhalation**

Remove the casualty to fresh air and keep him/her calm

Consult physician

### **4.4 Note to physician**

Treat symptomatically

## **5 Fire Fighting Measures**

### **5.1 Suitable extinguishing media**

Water spray jet, dry powder, foam, carbon dioxide

### **5.2 Specific hazards**

Consider dust explosion hazard

Formation of toxic and corrosive combustion gases (nitrogen oxides (NO<sub>x</sub>) possible

### **5.3 Protection of fire-fighters**

Precipitate gases/vapours/mists with water spray

## **6 Accidental Release Measures**

### **6.1 Environmental protection**

Do not allow to enter drains or waterways

### **6.2 Methods for cleaning up**

Collect solids (avoid dust formation) and hand over to waste removal

## **7 Handling and Storage**

### **7.1 Handling**

#### **7.1.1 Technical measures**

Local exhaust ventilation necessary

Take precautionary measures against electrostatic charging

Avoid dust formation; very high dust explosion hazard

#### **7.1.2 Suitable materials**

Stainless steel, aluminium, enamel, glass

### **7.2 Storage**

**7.2.1 Storage conditions** Temperature 2°-8°C

**7.2.2 Validity** 24 months

**7.2.3 Packaging materials** Tightly closing; Material: Aluminum can (lined with double PE bag)

## **8 Exposure Controls/Personal Protection**

**8.1 Engineering Measures** see 7.

### **8.2 Personal protective equipment**

#### **8.2.1 Respiratory protection**

In case of open handling or accidental release: particle mask or respirator with independent air supply

### **8.2.2 Hand protection**

Protective gloves (eg made of neopren, nitrile or butyl rubber)

### **8.2.3 Eye protection**

Safety glasses

## **9 Physical and Chemical Data**

**9.1 Colour** white to almost white

**9.2 Form** crystalline powder

**9.3 Odour** odourless

**9.4 Purity**  $\geq 98.0\%$

## **10 Stability and Reactivity**

**10.1 Stability:** Stable under the conditions mentioned in chapter 7, decomposition upon heating

**10.2 Conditions to avoid:** Light Humidity Heat

**10.3 Materials to avoid** Acids, Oxidizing agents, Bases

## **11 Toxicological Information**

### **11.1 Acute toxicity:**

LD50 > 5'000 mg/kg (oral, mouse)

LD50 > 5'000 mg/kg (oral, rat)

LD50 > 100 mg/kg (i.v., mouse)

LD50 > 100 mg/kg (i.v., rat)

**11.2 Local effects:** Eye: non-irritant (rabbit)

### **11.3 Chronic toxicity:**

NOEL 125 mg/kg/d (oral, rat; 12 months)

NOEL 300 mg/kg/d (oral, dog; 12 months)

**11.4 Mutagenicity:** Not mutagenic (various in vivo and in vitro test systems)

**11.5 Carcinogenicity:** Not carcinogenic

**11.6 Reproduction toxicity:** Not teratogenic, not embryotoxic (several species)

**11.7 Note:** Reduces fat absorption by inhibiting pancreatic lipase dose (clinical trials): 3 x 60 mg up to 3 x 120 mg per day per os elimination half-life after systemic application and high doses approx. 4-5 hours (i.v., 125 mg/kg/d, dog, 2 weeks) oral overdose may cause diarrhoea especially upon simultaneous uptake of fat no toxic effects have been observed during occupational handling

## **12 Ecological Information**

**12.1 Ready biodegradability:** Not readily biodegradable ~ 18 %, 29 days  
(FDA Technical Assistance Document No. 3.11)

**12.2 Ecotoxicity:** Moderately toxic for fish, test performed using solubilisers (rainbow trout)

LC50 (96 h) > 18.5 mg/l

NOEC (96 h) 18.5 mg/l

(FDA Technical Assistance Document No. 4.11)

Strongly toxic for planktonic crustaceans, test performed using solubilisers (Daphnia magna)

EC50 (48 h) 6.92 mg/l

NOEC (48 h) 1.95 mg/l

(FDA Technical Assistance Document No. 4.08)

Barely toxic for algae, test performed with water accommodated fractions (*Selenastrum capricornutum*)

EC50 (10 d) > 1.92 mg/l (saturation conc.)

NOEC (10 d) 1.92 mg/l (saturation conc.)

(FDA Technical Assistance Document No. 4.01)

Barely inhibitory on aerobic bacterial respiration (activated sludge)

NOEC (3 h) 50 mg/l (nominal concentration)

(OECD No. 209)

Barely toxic for earthworms (*Lumbricus terrestris*)

LC50 (28 days) ~ 907 mg/kg

Barely toxic for microorganisms (bacteria, fungi, cyanobacteria in pure culture)

NOEC 10 mg/l

(FDA Technical Assistance Document No. 4.02)

**12.3 Mobility:** Low mobility (Soil-Water, 25 °C)

KOC = 100605 (silty loam)

KOC = 176577 (clay loam)

KOC = 7010 (loam)

(FDA Technical Assistance Document No. 3.08)

**12.4 Air pollution:** observe local/national regulations

### **13 Disposal Considerations**

**13.1 Waste from residues:** incinerate in qualified installation with flue gas scrubbing  
observe local/national regulations regarding waste disposal

### **14 Transport Information**

**N/F**

### **15 Regulatory Information**

#### **15.1 Classification and labelling according to EU directives**

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

S61 Avoid release to the environment. Refer to special instructions/Safety

H411 Toxic to aquatic life with long lasting effects.

P273 Avoid release to the environment.

P391 Collect spillage.

P501 Dispose of contents/container to ... .

**15.2 Water hazard class (Germany):** 2: hazardous for water (own classification according to directive VwVwS of 17.05.1999)

### **16 Other Information**

**16.1 Use:** as pharmaceutical active substance for medical treatment of severe obesity

**16.2 Edition documentation:** The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.

