



# SAFETY DATA SHEET

Product name: Enstilar®  
Supersedes date: 2014-11-13  
P/N-no.:

Page: 1/10  
Revision Date: 2015-09-14  
SDS-ID: US-EN/2.0

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## SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### Product identifier

Product name: Enstilar®

### Relevant identified uses of the substance or mixture and uses advised against

Application: Pharmaceutical.

### Details of the supplier of the safety data sheet

Supplier: LEO Pharma A/S  
Industriparken 55  
DK-2750 Ballerup  
Tel: +45 4494 5888

Responsible for material safety data sheet authoring: SDS\_info@dhigroup.com

### Emergency telephone number

Emergency telephone: National Capital Poison Center: 1-800-222-1222

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## SECTION 2: HAZARDS IDENTIFICATION

### Classification of the substance or mixture

This Product is Hazardous under the OSHA Hazard Communication Standard.

Classification according to OSHA HCS (2012):

OSHA 2012: Flam. Aerosol 1;H222

### Label elements

Label in accordance with OSHA HCS (2012):



Danger

H222 Extremely flammable aerosol.

P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

P211 Do not spray on an open flame or other ignition source.

P251 Pressurized container: Do not pierce or burn, even after use.

P410 + P412 Protect from sunlight. Do not expose to temperatures exceeding 50°C/122°F.

Pressurised container: May burst if heated.

This product is covered by the OSHA Hazard Communication Rule 29, CFR 1910.1200

### Other hazards

PBT/vPvB: Not relevant.

Other: Degreasing to skin. In high concentrations, vapors and spray mists are narcotic and may cause headache, fatigue, dizziness and nausea. When sprayed on a naked flame or any incandescent material the aerosol vapors can be ignited. Aerosol containers can explode when heated, due to excessive pressure build-up. The product contains volatile, organic compounds which have a photochemical ozone creation potential.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### Mixtures

The product contains: Active pharmaceutical substance, propellants, organic solvents and additives.

This product contains no ingredient listed on the NTP, OSHA, IARC or California Proposition 65 carcinogen lists.

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## OSHA 2012:

<u>%:</u>	<u>CAS-No.:</u>	<u>EC No.:</u>	<u>Chemical name:</u>	<u>Hazard classification:</u>
25-50	8009-03-8	232-373-2	Petrolatum	-
25-50	106-97-8	203-448-7	Butane	Flam. Gas 1;H220 Press. Gas
25-50	115-10-6	204-065-8	Dimethyl ether	Flam. Gas 1;H220 Press. Gas
1-2.5	25231-21-4		(Poly[oxy(methyl-1,2-ethanediyl)], α - octadecyl-ω-hydroxy-)	-
1-2.5	8042-47-5	232-455-8	Paraffin oil	-
<0.1	5593-20-4	227-005-2	Betamethasone dipropionate	Repr. 2;H361 STOT RE 2;H373
<0.1	147657-22-5		Calcipotriol monohydrate	Acute Tox. 2;H330 Acute Tox. 2;H300 Acute Tox. 3;H311 STOT RE 1;H372
<0.1	10191-41-0	233-466-0	2H-1-Benzopyran-6-ol, 3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-	-

References: The full text for all hazard statements is displayed in section 16.

## SECTION 4: FIRST AID MEASURES

### Description of first aid measures

**Burns:** Flush with water immediately. While flushing, remove clothes which do not adhere to affected area. Call an ambulance. Continue flushing during transport to hospital.

**Inhalation:** Move injured person into fresh air and keep person calm under observation. If uncomfortable: Seek hospital and bring these instructions.

**Skin contact:** Remove contaminated clothes and rinse skin thoroughly with water. In case of eczema or other skin disorders: Seek medical attention and bring these instructions.

**Eye contact:** Immediately flush with plenty of water for up to 15 minutes. Remove any contact lenses and open eyelids widely. If irritation persists: Continue flushing during transport to hospital. Bring along these instructions.

**Ingestion:** Immediately rinse mouth and drink plenty of water. Keep person under observation. If person becomes uncomfortable seek hospital and bring these instructions.

### Most important symptoms and effects, both acute and delayed

**Symptoms/effects:** See section 11 for more detailed information on health effects and symptoms.

### Indication of any immediate medical attention and special treatment needed

**Medical attention/treatments:** Not known.

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## SECTION 5: FIREFIGHTING MEASURES

### Extinguishing media

Extinguishing media: Extinguish with carbon dioxide or dry powder. Cool containers exposed to heat with water spray and remove container, if no risk is involved.

### Special hazards arising from the substance or mixture

Specific hazards: Aerosol containers can explode when heated, due to excessive pressure build-up.

### Advice for firefighters

Protective equipment for fire-fighters: Selection of respiratory protection for fire fighting: follow the general fire precautions indicated in the workplace.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

Personal precautions: Do not smoke or use open fire, or other sources of ignition. Avoid inhalation of vapors and contact with skin and eyes. Follow precautions for safe handling described in this safety data sheet.

### Environmental precautions

Environmental precautions: Avoid discharge into drains, water courses or onto the ground. Aerosol containers should not be dumped in nature.

### Methods and material for containment and cleaning up

Spill Cleanup Methods: Absorb spillage with non-combustible, absorbent material.

### Reference to other sections

References: For personal protection, see section 8. For waste disposal, see section 13.

## SECTION 7: HANDLING AND STORAGE

### Precautions for safe handling

Safe handling advice: Avoid inhalation of vapors and contact with skin and eyes. Observe good chemical hygiene practices.

Technical measures: Work practice should minimize contact. Do not smoke or use open fire or other sources of ignition.

Technical precautions: Mechanical ventilation may be required. Provide easy access to water supply or an emergency shower.

### Conditions for safe storage, including any incompatibilities

Technical measures for safe storage: Follow rules for flammable liquids.

Storage conditions: Store in tightly closed original container in a well-ventilated place. Protect from light. Do not store near heat sources or expose to high temperatures.

### Specific end use(s)

Specific use(s): Not relevant.

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## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

Occupational exposure limits:

<u>CAS-No.:</u>	<u>Chemical name:</u>	<u>As:</u>	<u>Exposure limits:</u>	<u>Type:</u>	<u>Notes:</u>	<u>References:</u>
106-97-8	Butane, all isomers	-	1000 ppm	STEL	15min	ACGIH
106-97-8	n-Butane	-	800 ppm	1900 mg/m3 TWA	-	NIOSH

### Exposure controls

Engineering measures: Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of inhalation of vapors.

Personal protection: Personal protection equipment should be chosen according to the ANSI standards and in discussion with the supplier of the personal protective equipment.

Respiratory equipment: In case of inadequate ventilation use suitable respirator. Use respiratory equipment with combination filter, type AXP3.

Hand protection: Risk of contact: Wear protective gloves.  
Nitrile gloves are recommended, but be aware that the liquid may penetrate the gloves. Frequent change is advisable. Other types of gloves can be recommended by the glove supplier.

Eye protection: Risk of contact: Wear goggles/face shield.

Skin protection: Wear apron or protective clothing in case of contact.

Hygiene measures: When using do not eat, drink or smoke. Wash hands after handling. Change contaminated clothing.

Environmental Exposure Controls: Not available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

Appearance: aerosol

Color: white

Odor: Ether.

pH: Not available.

Boiling point: Not available.

Flash point: Not available.

Vapor pressure: Not available.

### Other information

Other data: Not available.

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## SECTION 10: STABILITY AND REACTIVITY

### Reactivity

Reactivity: None known.

### Chemical stability

Stability: Stable under normal temperature conditions.

### Possibility of hazardous reactions

Hazardous Reactions: None known.

### Conditions to avoid

Conditions/materials to avoid: Heat, sparks, flames.

### Incompatible materials

Incompatible materials: Strong oxides.

### Hazardous decomposition products

Hazardous decomposition products: None in particular.

## SECTION 11: TOXICOLOGICAL INFORMATION

### Information on toxicological effects

Inhalation: Vapors and spray mist may irritate throat and respiratory system and cause coughing. In high concentrations, vapors and spray mists are narcotic and may cause headache, fatigue, dizziness and nausea.

Skin contact: Prolonged contact may cause dryness of the skin.

Eye contact: May irritate and cause redness and pain.

Ingestion: May irritate and cause malaise. May be absorbed in the body and cause dizziness, nausea and vomiting.

### Specific effects:

This product contains no ingredient listed on the NTP, OSHA, IARC or California Proposition 65 carcinogen lists.

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## SECTION 12: ECOLOGICAL INFORMATION

### **Toxicity**

**Ecotoxicity:** The ecotoxicity of the product has not been stated. The product is not expected to be hazardous to the environment.

### **Persistence and degradability**

**Degradability:** The degradability of the product has not been stated.

### **Bioaccumulative potential**

**Bioaccumulative potential:** No data available on bioaccumulation.

### **Mobility in soil**

**Mobility:** No data available.

### **Results of PBT and vPvB assessment**

**PBT/vPvB:** Not relevant.

### **Other adverse effects**

**Other adverse effects:** The product contains volatile, organic compounds which have a photochemical ozone creation potential.

## SECTION 13: DISPOSAL CONSIDERATIONS

### **Waste treatment methods**

Dispose of waste and residues in accordance with local authority requirements.

**Waste from residues:** This product, if discarded, may be considered a characteristic hazardous waste under RCRA (ignitable waste, D001).

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## SECTION 14: TRANSPORT INFORMATION

IATA: ID 8000

DOT:

### **UN number**

UN-No: 1950

### **UN proper shipping name**

Proper Shipping Name: AEROSOLS, flammable

### **Transport hazard class(es)**

Class: 2  
Division 2.1

### **Packing group**

PG: -

### **Environmental hazards**

Marine pollutant: No

Environmentally Hazardous substance: No

### **Special precautions for user**

Special precautions: None known.

### **Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Transport in bulk: Not relevant.

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## SECTION 15: REGULATORY INFORMATION

### Safety, health and environmental regulations/legislation specific for the substance or mixture

Special provisions: TSCA: Not listed. Betamethasone dipropionate ; Calcipotriol monohydrate.

Pharmaceutical applications are regulated by the FDA, and are therefore exempt from EPA TSCA regulations.

SARA (311/312) Hazard categories:

Fire Hazard: Yes.

Reactive Hazard: No.

Pressure Hazard: Yes.

Acute Health: Yes.

Chronic Health: No.

This product contains no ingredient listed on the NTP, OSHA, IARC or California Proposition 65 carcinogen lists.

CAA: TQ = 10,000 lbs. (Dimethyl ether; Butane)

NFPA Rating: Health: 1 Fire: 4 Reactivity: 0 Other: -

National regulation:

The following lists and legislation have been checked:

The Code of Federal Regulation, Title 29, part 1910. Occupational Safety and Health Standards, Hazard Communication, with amendments.

Threshold Limit Values (2015), ACGIH, by the American Conference on Governmental Industrial Hygienists.

The Code of Federal Regulation, Title 29, part 1910. Occupational Safety and Health Standards, Air contaminants (OSHA), with amendments.

NIOSH Pocket Guide to Chemical Hazards.

The Code of Federal Regulation, Title 40, part 261.33. Identification and listing of hazardous waste.

The Code of Federal Regulation. Title 40, part 355.50. Emergency Planning and Notification.

The Code of Federal Regulation. Title 40, part 302.4. Designation, Reportable Quantities, and Notification.

The Code of Federal Regulation. Title 40, part 68.130. Chemical Accident Prevention Provisions.

The Code of Federal Regulation. Title 40, part 372.65. Toxic Chemical Release Reporting: Community Right to Know.

U.S. Department of health and human services: 2014 - Report on Carcinogens - 13th Edition.

International Agency for Research on Cancer (IARC): IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Lyon: IARC, World Health Organization.

State of California. Environmental Protection Agency. California Proposition 65, with amendments.

### Chemical Safety Assessment in compliance with Regulation (EC) No 1907/2006 (REACH)

CSA status: Not relevant.

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## SECTION 16: OTHER INFORMATION

The user must be instructed in the proper work procedure and be familiar with the contents of these instructions.

The following sections contain revisions or new statements: 1, 2, 3, 8, 11, 14, 15, 16.

Additional information: Classification according to HCS 2012: Calculation method.

Wording of H-statements:

H220	Extremely flammable gas.
H222	Extremely flammable aerosol.
H229	Pressurised container: May burst if heated.
H300	Fatal if swallowed.
H311	Toxic in contact with skin.
H330	Fatal if inhaled.
H361	Suspected of damaging fertility or the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.
H372	Causes damage to organs through prolonged or repeated exposure if inhaled.
H373	May cause damage to organs through prolonged or repeated exposure.

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The information on this data sheet represents our current data and is reliable provided that the product is used under the prescribed conditions and in accordance with the application specified on the packaging and/or in the technical guidance literature. Any other use of the product which involves using the product in combination with any other product or any other process is the responsibility of the user.

Made by DHI - Environment and Toxicology, Agern Allé 5, DK-2970 Hørsholm, Denmark.  
[www.dhigroup.com](http://www.dhigroup.com).

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