



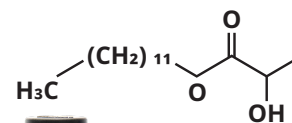
Lauryl Lactate HP, USDMF

Applications

Lauryl lactate is widely used in the pharmaceutical industry and specially for Topical products (i.e. Transdermal patches).

Following is a list of key applications:

- Emollient
- Emulsifier
- Excipient
- Humectant
- Penetration enhancer



General Information

Pharmacopeia Status	: In-house product
CAS No.	: 6283-92-7
EC No.	: 228-504-8
Appearance / Description	: Clear Liquid
Molecular Formula	: $\text{C}_{15}\text{H}_{30}\text{O}_3$
Molecular Mass	: 258.4 g/mol

Marketed Formulation

- Norelgestromin & Ethinyl Estradiol transdermal patch
- Norelgestromin transdermal patch and more...

Quality and Regulatory Support

- GMP and ISO certification
- EXCiPACT certification
- Nitrosamine impurity risk assessment
- Elemental impurity risk assessment
- Residual solvent declaration
- Genotoxic impurity declaration
- Vendor questionnaire and site audit
- CMC documentation
- Regulatory queries

Key Product Attributes

- Manufacturing and packing under GMP environment
- Low Lactic acid contents

Pack Mode

500 gm glass bottle

DMF (Drug Master File)

USDMF registered product (DMF # 31766)

Stability and Storage Conditions

Stable under recommended conditions. Keep container tightly closed in a cool, dry and well-ventilated place.

Safety and Handling Information

Avoid contact with skin and eyes. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. A laboratory fume hood or other appropriate form of local exhaust ventilation should be used to avoid exposure. If exposed, evacuate personnel to safe areas. Wash affected area with soap and water. Consult a physician if any exposure symptoms are observed.

Product Specifications (In-house)

Description	Clear liquid
Colour	Light yellow
Purity (By GC)	Min. 70.0%
Acid value, KOH mg/g	5 max
Saponification value mg, KOH/g	205 – 225
Specific gravity, 25°C	0.91 - 0.92
Lauryl alcohol	15.0% max
Lactic acid	1.0% max
Lauryl lactyl lactate	14.0% max

Shipping Information

By Sea, Air and Road

Nature: Hazardous

UN No.: 3077

Transport Hazard Class: 9

Packaging Group: III

See the Material Safety Data Sheet on www.finarchemicals.com

Note: The information contained herein is to our best knowledge true and accurate, but all recommendations or suggestions are made without guarantees since the conditions of use are beyond our control. Finar disclaims any liability incurred with the use of this data or suggestions.

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