

SIMALINE™ L80

Liquid emulsifier for Geltrap™ “Gel-in-oil”
and traditional W/O emulsion

SIMALINE™ L80

Sorbitan oleate /
PEG-30 Dipolyhydroxystearate

CAS number 1338-43-8 / 70142-34-6

Regulatory status **European Pharmacopeia-compliant raw materials**

Physical state **Liquid**

Applications Marketing Authorization /
Medical Device / Dermo-cosmetic

Administration routes Topical / Transdermal (skin) /
Mucosal (vaginal, rectal)

Dosage forms Geltrap™, W/O emulsion

Geltrap™
dosage form

→ A combination of
IID-listed & Ph.Eur.
excipients

❑ An innovative dosage form with strong technical performances

A Geltrap™ is the result of the enveloping of a gel-textured aqueous phase in a lipidic film, stabilized by a polymeric W/O emulsifier

→ A **vehicle for polar solvents**, even at high concentrations

Internal Aqueous phase > 80%

Gel = Water - **Polar solvents** - **Sepineo™ Polymer**

Sepineo™ P 600 (liquid)
or Sepineo™ D.E.R.M (powder)
or Sepineo™ PHD 100 (powder)

IID registered - DMF
DMF
DMF (ongoing)

→ **Unique texture**, for an optimal patient compliance



50%
PEG-400

40%
Transcutol® P

80%
Propylene glycol

40%
Glycerin

With a nice sensorial profile !

→ **Added benefits**
Moisturizing
Emollient
Water resistance

External fatty phase 5 - 20%

Oils - **W/O surfactants**

Simaline™ L80 PEG-30 Dipolyhydroxystearate
(polymeric surfactant)
Sorbitan Oleate

Ph.Eur.

Ph.Eur., USP-NF

→ Easy and versatile formulation process

A robust **polymeric surfactant**, opening the possibility of **emulsification in all kind of settings**

- From **room-temperature to hot process**
- From **low shear to high shear**

Improved aesthetics and sensorial profile, even in solvent-rich formulations

Building a dosage form to solubilize and deliver a specific API into the skin can lead you to use excipients negatively impacting the touch of your final product. With the Geltrap™ technology, you can formulate these same excipients and still ensure a positive patient experience.



- **Fresh**
- **Non-greasy, non-sticky**
Even with **40% Glycerin**
- **Comfort, cushion effect**



- **Easy pick-up**
- **Easy skin spreading**

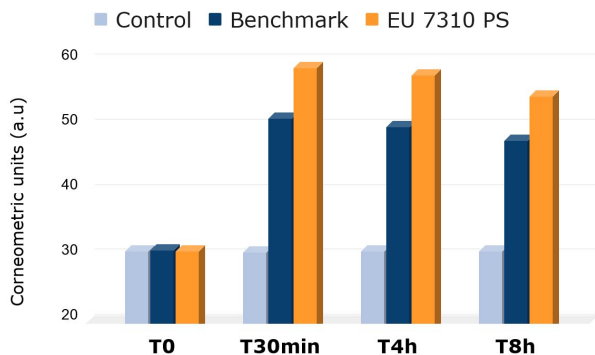


Cream-like aspect
White, shiny,
smooth surface

Added benefits for medicated skincare

→ Superior moisturizing properties

A **Geltrap with only 20% Glycerin** achieve **significantly better moisturizing results** compared to a benchmark with 40% Glycerin



Clinical testing: 20 volunteers with dry skin

→ Emollient vehicle



A **Geltrap with 10% of oil** shows the **same non-drying properties** as an **O/W or W/O emulsion with 20% oil**

In vitro testing

→ Water-resistance

Useful property for vaginal-rectal applications, to prevent the early wash-out of the drug by body fluids

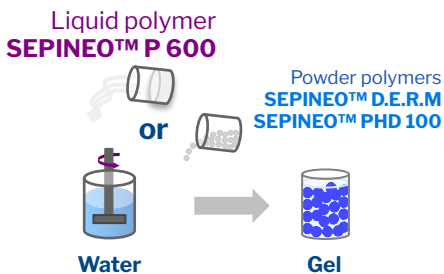
In vitro testing



Manufacturing

1 Prepare the aqueous phase - Gel

a) Add **SEPINEO™** polymer to water



b) Add solvents to the gel

2 Prepare the lipophilic phase



c) Mix Oils + W/O surfactants

- **Simaline™ L 80** (liquid form)
- ~ 1.5%
- Room-temperature* or hot process

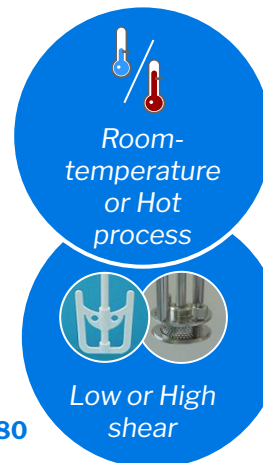
*Heating Simaline™ L80 at 50°C is recommended before use

3 Emulsification



d) **Gel-in-oil**

W/O interface stabilization by W/O emulsifier **Simaline™ L 80**



Room-temperature or Hot process

Low or High shear

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Note:

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