

# Skin-friendly textures



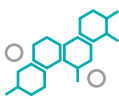
# Caring for patients

Patient preferences and needs as well as therapeutic indication should be considered at early stage of development of topical or transdermal formulations.



To increase adherence to skin treatments, it is important to consider patient's needs, when designing the dosage form:

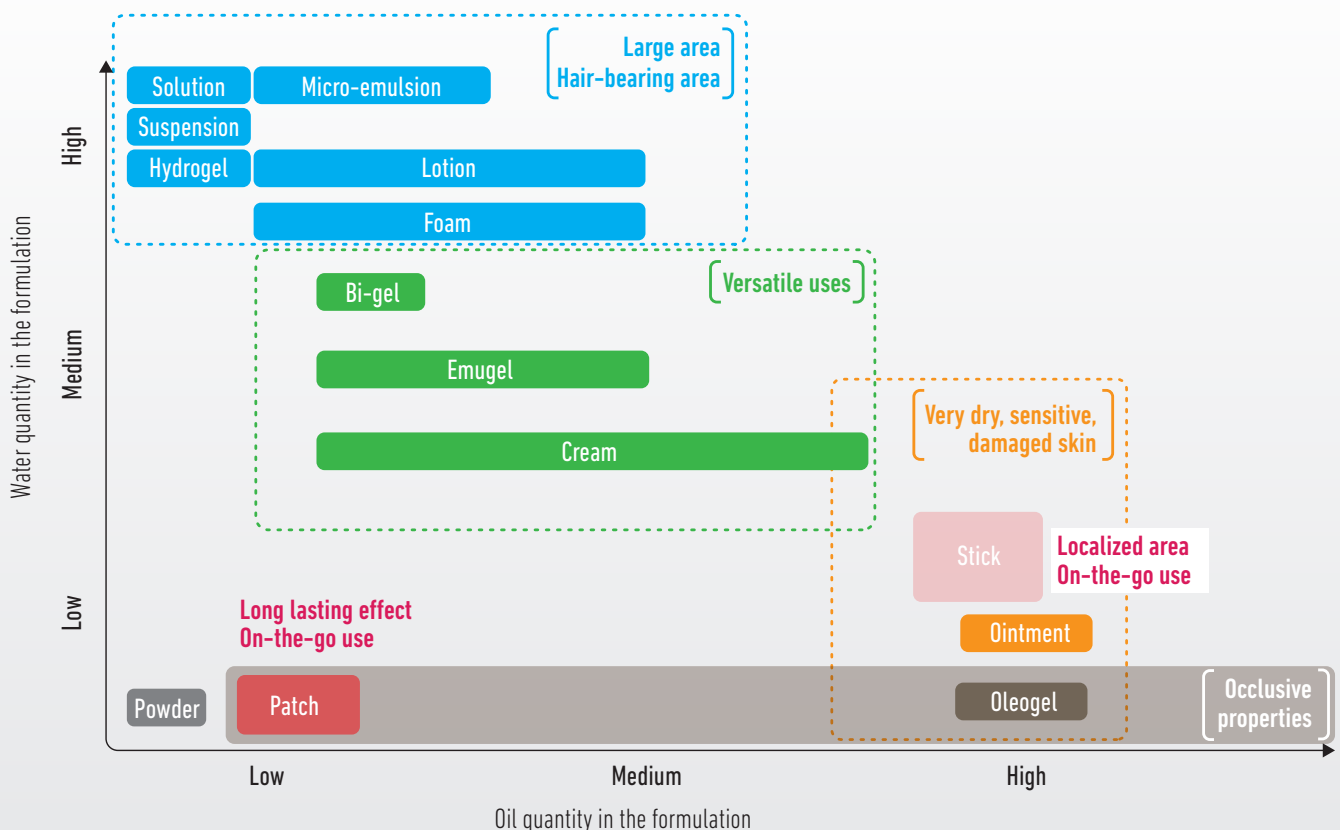
*On which part of the body will the product be applied? Is it to be applied on large areas or on a very localized spot? Is it a hair-bearing area? Is the skin sensitive or dry? Are there lesions on the skin? What is the skin pH? Is it to be used on-the-go? Is it to be applied just before getting dressed?*



The therapeutics also guides the choice of the dosage form:

*For which indication is it used? Is it a chronic or an acute disease? How many times should the product be applied daily? Should the dose be delivered with a metered device? How long the treatment should last? What is the therapeutic dose?*

## Patient-centered mapping of topical dosage forms



At Gattefossé, we care for patient considerations and expectations for sustainable, natural and safe excipients.

Our excipients are mainly derived from vegetable, renewable origin. We are committed to integrating the use of certified sustainable palm oil. Our range of functional excipients includes PEG-free emulsifiers, thickeners, oily vehicles and solubilizers.



# Gattefossé solutions for each dosage form

## Emulsion-based semi-solid dosage forms

### Selecting the most appropriate emulsifier

Our emulsifiers are all-in-one self-emulsifying bases, enabling the preparation of homogenous emulsions with pleasant textures. Guidance is provided to help selecting the most appropriate emulsifier depending on the active ingredient properties, the final dosage form and the quantity of oil our emulsifiers can disperse.

Drug physico-chemical properties			
Lipophilic	Heat sensitive	Water sensitive	Oxidation sensitive
For high oil content formulations, select among Apifil <sup>®</sup> , Gelot <sup>™</sup> 64 and Sedefos <sup>™</sup> 75	For a room temperature process, use Plurol <sup>®</sup> Diisostearique	Make anhydrous or low water content formulations with Sedefos <sup>™</sup> 75	Prefer low shear two-pot process to minimize air incorporation using Gelot <sup>™</sup> 64, Tefose <sup>®</sup> 1500 or Tefose <sup>®</sup> 63

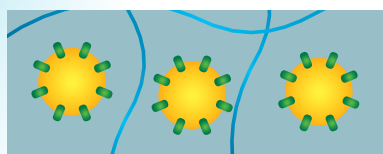
Emulsifier	Dosage form							Quantity of oil our emulsifiers can disperse		
	Lotion	Foam	Emulgel	Cream	Rich cream	Balm	Stick	Mineral oil	Vegetable oil	Medium chain triglycerides
Oil-in-water HLB = 9-10	Apifil <sup>®</sup>			*	*		***	25-40%	25-40%	25-40%
	Gelot <sup>™</sup> 64		*	**	**	***	***	25-40%	10-20%	3-6%
	Sedefos <sup>™</sup> 75		***			**	***	25-40%	10-20%	10-20%
	Tefose <sup>®</sup> 1500	***			*			10-20%	10-20%	10-20%
	Tefose <sup>®</sup> 63		**	***	**	**			10-20%	10-20%
Water-in-oil HLB = 4-5				**		***	***	10-20%	3-6%	3-6%

### Adding a stabilizing agent helps guaranteeing the emulsion stability over its shelf-life

An emulsion consists of an oily phase, an aqueous phase and an emulsifier and is, by nature, an unstable thermodynamic system.

To ensure shelf-life stability of final dosage forms, it might be necessary to stabilize the system by acting on one or more of its components.

The use of a **gelling agent** in the aqueous phase increases its viscosity dramatically. The polymer chains stiffen the aqueous phase, preventing oil droplet movement.

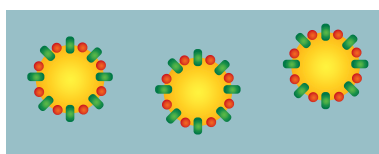


Emulsifier, Oil phase, Aqueous phase, Gelling agent

**Co-emulsifiers** reinforce the action of the emulsifier at the interface between the aqueous and oily phases.

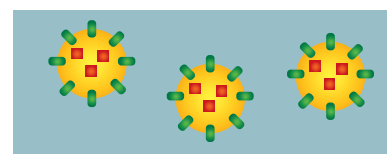
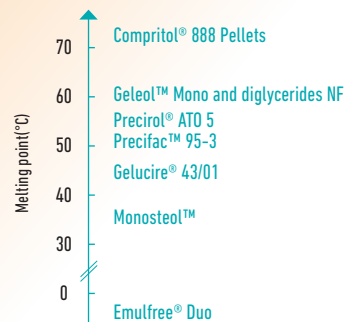
Choose among our win-win combinations:

- Tefose<sup>®</sup> 63 + Labrafil<sup>®</sup> M 1944 CS (2:1)
- Tefose<sup>®</sup> 1500 + Labrafil<sup>®</sup> M 2130 CS (2:1)
- Gelot<sup>™</sup> 64 + Emulcire<sup>™</sup> 61 WL 2659 (1:1)
- Plurol<sup>®</sup> Diisostearique + Plurol<sup>®</sup> Oleique CC 497



Emulsifier, Oil phase, Aqueous phase, Co-emulsifier

Increasing the viscosity of the oily phase reduces the risk of oil droplet coalescence. This can be achieved with solid **thickeners** that recrystallize in the oil droplet or liquid **oil-stabilizing agent**.



Emulsifier, Oil phase, Aqueous phase, Thickener

## Gel-based semi-solid dosage forms

Depending on the active pharmaceutical ingredient properties, the choice towards conventional oleogels or hydrogels can be made. Alternatively, innovative bi-gels can be prepared using Emulfree® Duo.

Drug physico-chemical properties			
Lipophilic	Heat sensitive	Water sensitive	Oxidation sensitive
Prefer oleogel or bi-gel	For a room temperature process, prefer bi-gel and use Emulfree® Duo	Prefer oleogel or anhydrous gel	Prefer low shear process

**Hydrogels** are obtained with carbomers, hydroxyethylcelluloses or hydroxypropylcelluloses. Clear gels are obtained with Transcutol® P, whatever its concentration and the gelling agent used.

**Bi-gels** consist of an intimate mixture of an aqueous gel and an oily gel. Using Emulfree® Duo as oil-stabilizing agent, bi-gels are easily obtained at room temperature.

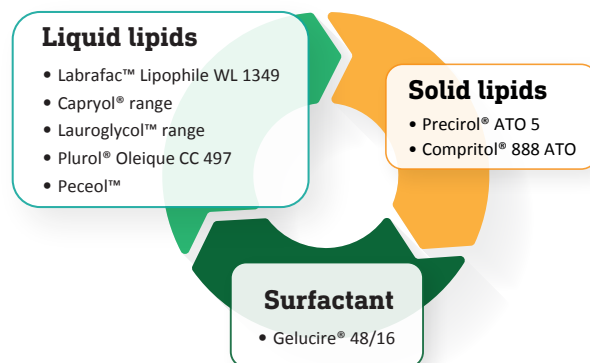
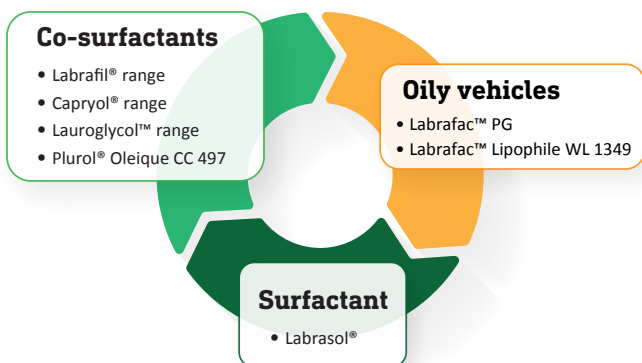
**Oleogels** are obtained by adding thickeners to the oily vehicles.

## Liquid dosage forms

**Microemulsions** are thermodynamically stable systems, formed spontaneously by gentle mixing of their components: oily vehicle, surfactant/co-surfactant and water. Microemulsions can be used as such, or for the preparation of innovative pharmaceutical foams using propellant-free devices.

## Solid dosage forms

**Lipid-based nanocarriers** are solid at room and body temperature, enabling the inclusion and protection of the drug, while facilitating its delivery to the skin. It can be used as such or serve as an intermediate product in other topical formulations, such as suspension, gel or patch.



## A full range of functional excipients for topical and transdermal dosage forms

### Solvent - Penetration enhancers

- Capryol® 90 \*
- Capryol® PGMC \*
- Labrafac™ MC60 \*
- Labrasol®
- Lauroglycol™ 90 \*
- Lauroglycol™ FCC \*
- Maisine® CC \*
- Peceol™ \*
- Plurol® Oleique CC 497 \*
- Transcutol® P \*

### Emulsifiers

- Apifil®
- Gelot™ 64
- Plurol® Diisostearique \*
- Sedefos™ 75
- Tefose® 1500
- Tefose® 63

### Co-emulsifiers

- Emulcire™ 61 WL 2659
- Labrafil® M 1944 CS
- Labrafil® M 2125 CS
- Labrafil® M 2130 CS
- Plurol® Oleique CC 497 \*

### Surfactants

- Gelucire® 48/16
- Labrasol®

### Co-surfactants

- Capryol® 90 \*
- Capryol® PGMC \*
- Lauroglycol™ 90 \*
- Lauroglycol™ FCC \*
- Labrafil® M 1944 CS
- Labrafil® M 2125 CS
- Labrafil® M 2130 CS
- Plurol® Oleique CC 497 \*

### Stabilizing agent - Thickeners

- Emulfree® Duo \*
- Compritol® 888 Pellets \*
- Geleol™ Mono and Diglycerides NF \*
- Gelucire® 43/01 \*
- Monosteol™ \*
- Precifac™ 95-3 \*
- Precirol® ATO 5 \*

### Oily vehicles - Emollients

- Gelucire® 43/01 \*
- Labrafac™ PG \*
- Labrafac™ Lipophile WL 1349 \*
- Peceol™ \*
- Suppacire® A \*

# Supporting your product development

Appearance

Immediate contact

Upon application

After absorption

Excipient selection

Formulation development

Sensorial analysis

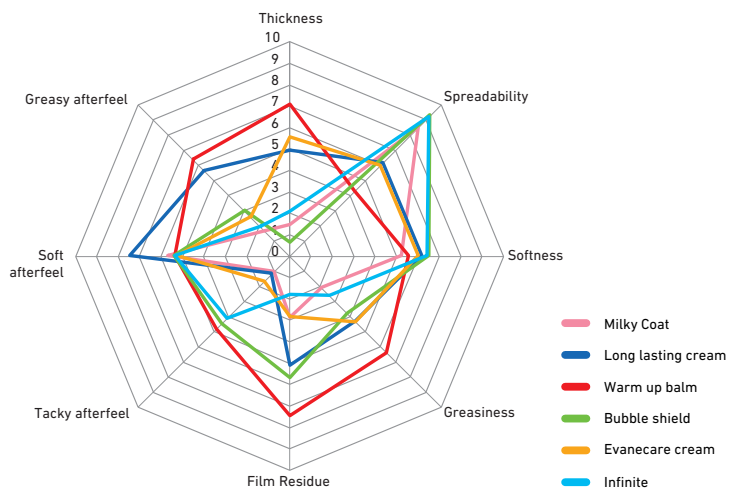
In vitro drug release and permeation

## Sensorial analysis: A tool to formulate patient-friendly textures

Sensorial analysis is a scientific discipline that applies the principles of experimental design and statistical analysis to measure, analyze, and interpret the characteristics of a product as they are perceived by the senses. Gattefossé has developed validated methods and established an in-house trained panel.

Using this approach, we can evaluate the sensorial properties of prototype formulations to assess the influence of raw materials in the formulation, evaluate the main texture characteristics of our excipients, compare prototypes with market references, understand market preferences, construct a broad texture database, and help our customers develop their own formulations.

We have developed a kit of placebo formulations to illustrate the unlimited range of textures our functional excipients provide. Request your demo!



## Our technical expertise: A shortcut for your development

Gattefossé is committed to knowledge sharing through conferences, webinars, publications, technical brochures and guidelines available on our website. Our aim is to give formulators all the clues for a proper use of lipid excipients in formulations to optimize drug delivery to the skin.

With a worldwide network of technical representatives and more than 20 high-level scientists and technicians in our Technical Centers of Excellence in China, France, India and the USA, we continuously work to deepen our understanding of excipients and drug behavior in the formulation and how it interacts with the skin.

We have met the challenges of formulating so many drugs, why not yours?

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People make our name