

# Gattefossé expands its offer with the launch of three new pharmaceutical excipients



**Press Release** 

# Lyon, France, October 28th, 2021

Gattefossé, supplier of specialty ingredients for the health and beauty industries, announces the launch of three new pharmaceutical ingredients: Labrafac™ MC60 and Gelucire® 59/14, for the for oral administration route and Emulfree® Duo for the topical administration route.

The group celebrated its 140<sup>th</sup> anniversary last year and has stayed the course despite the past two years which were marked by the global pandemic and resulting health crisis.

With the launch of these three excipients, Gattefossé demonstrates its commitment to exploring the very best of nature and science since 1880.

# Rare and unprecedented news

Launching three ingredients in the same year is unusual in the pharmaceutical ingredient industry, given the long and complex research & development and regulatory demands that are placed on the developer. But once completed, new ingredients can successfully and safely address many formulation challenges that are present in the industry.

To ensure their international launches and successes, Labrafac™ MC60, Gelucire® 59/14 and Emulfree® Duo conform to all regulatory requirements.



"This last quarter of 2021 is both exciting and challenging. We are proud to launch three new lipidic excipients, expand our range and offer new solutions to address our customers' needs.

With everything we do, we always look to innovate, while remaining dedicated to providing solid customer support and technical assistance

As specialists in lipid chemistry, we provide formulation expertise supported by our reliable, effective and safe ingredients", says Eduardo de Purgly, Chief Executive Officer of Gattefossé group.



# **Snapshots of our new products**

#### Labrafac™ MC60

Labrafac™ MC60 is used to enhance oral bioavailability of poorly water-soluble and poorly permeable drugs. It acts as a solubilizer and intestinal permeation enhancer for a wide variety of molecules.

Labrafac™ MC60 can successfully be used in lipid-based Type I (oily solutions) and Types II and III (SEDDS) formulations.

#### Gelucire® 59/14

Gelucire® 59/14 is a self-emulsifying excipient used for oral bioavailability enhancement of poorly water-soluble drugs, thanks to its high solubilization capacity. Upon contact with aqueous or digestive media, it spontaneously forms a fine dispersion.

Gelucire® 59/14 is supplied in pellets, making it easy to handle and an interesting addition to Gattefossé's Gelucire® range of products. A key difference to other Gelucire® grades is its higher melting point.

#### Emulfree® Duo

Emulfree® Duo is the new functional excipient developed by Gattefossé. It is dedicated to topical drugs and medications which are applied on the body or to mucosal areas.

As a mixture of excipients, Emulfree® Duo is a ready-to-use PEG-free system. It has been designed to stabilize the oil phase within a bi-gel by ensuring fine and homogeneous dispersions in the aqueous phase. This new excipient offers unique and innovative textures in formulations while improving treatments and patient adherence.

Need further information? Dedicated product sheets are available on the following pages.

Gattefossé is also participating at CPhI Worldwide with our virtual exhibition;

<u>click here</u> to visit our profile!

## **About Gattefossé**

<u>Gattefossé</u> is a French company that develops, manufactures and sells specialty ingredients to the personal care and pharmaceutical industries. Specializing in lipid chemistry and plant extraction, the group offers recognized formulation expertise through its four application laboratories located on three continents.

Gattefossé markets its products in more than 60 countries through its 12 affiliated companies combined with a network of local agents and distributors who provide solid technical support to customers.

The company remains a family-run, independent business since its creation in 1880.

#### **Media Relations**

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# New oral excipient in Gattefossé's portfolio: Labrafac™ MC60





Watch the video

**Press Release** 

Gattefossé expands its range of high quality, functional excipients for oral bioavailability enhancement with Labrafac™ MC60, glycerol monocaprylocaprate.

What is Labrafac™ MC60 used for?

<u>Labrafac™ MC60</u> is used for oral bioavailability enhancement of poorly water-soluble, poorly permeable drugs. It acts as a solubilizer for a wide range of molecules and as an intestinal permeation enhancer.

# What is the chemistry behind Labrafac™ MC60?

With its unique and respected expertise in lipid chemistry, Gattefossé has developed a robust and validated esterification process, between glycerol and capric and caprylic fatty acids, to produce a high quality, highly reproducible excipient composed of mono- and di-glycerides. Labrafac™ MC60 has mild surfactant properties and an HLB=5.

#### What is the regulatory status and precedence of use of this excipient?

Labrafac™ MC60 complies to USP-NF and Ph. Eur. Pharmacopoeias. Glycerol monocaprylocaprate has been used for decades in the pharmaceutical industry in numerous drug products around the world.



"Our worldwide customers are looking forward to this product. The chemistry of this compound is in the core business of Gattefossé Pharmaceuticals and complementary to our existing range of excipients. We put our expertise in lipid chemistry to deliver a high quality, highly reproducible glycerol monocaprylocaprate"

says Régis Cazes, Group Director Gattefossé Pharmaceuticals

"In Saint-Priest application laboratories, we have developed different formulations. A very straightforward one consisted of dutasteride and Labrafac $^{\text{TM}}$  MC60. We also developed SEDDS formulations with different model drugs such as terfenadine and cinnarizine. In each case, our formulations were able to solubilize and keep the drugs in solution throughout in vitro testing that simulated gastro-intestinal conditions" explains Elsa Gattefossé, Pharm.D Formulation Scientist.





"Labrafac<sup>TM</sup> MC60 has tremendous potential, not only with poorly water-soluble BCS Class II drugs, due to its high solubilization capacity, but also with poorly permeable drugs (BCS Class III), as it is a reversible tight junction opener. With its unique functionalities, Labrafac<sup>TM</sup> MC60 complements our wide range of excipients for oral bioavailability enhancement, and opens opportunities to work with challenging molecules" declares Camille Dumont, PhD Formulation Scientist.



# New self-emulsifying excipient in Gattefossé's portfolio, Gelucire® 59/14



Gattefossé expands its range of high quality, functional excipients for oral bioavailability enhancement with Gelucire® 59/14, a solid surfactant.

# What is Gelucire® 59/14 used for?

<u>Gelucire® 59/14</u> is a self-emulsifying excipient used for oral bioavailability enhancement of poorly water-soluble drugs, owing to its high solubilization capacity.

## What is the chemistry behind Gelucire® 59/14?

It is a mixture of lauroyl PEG-32 glycerides EP/NF and PEG 6000 EP/NF with surfactant properties (HLB= $14\pm1$ ).

# What is the regulatory status and precedence of use of this excipient?

Both components are compliant to European and US pharmacopeias and are listed in the FDA inactive ingredient database.

# How does it compare to other Gelucire® grades?

The melting point is the key difference. Gattefossé's range of Gelucire® consists of three grades of self-emulsifying excipients: Gelucire® 44/14, Gelucire® 50/13 and Gelucire® 59/14, having melting points of about 44, 50 and 59°C, respectively.

Gelucire® 59/14 is supplied in pellets, making it easy to handle and an interesting addition to the Gelucire® range.



"In our Technical Center of Excellence in Mumbai, we conduct studies with our Gelucire® range to enhance drug bioavailability. With this new grade of Gelucire® 59/14 we offer our customers a product with a high melting point and high HLB value. Depending on drug properties, formulation process and desired final dosage form, our customers can choose the grade of Gelucire® that best suits their needs."

explains Sunil Bambarkar, Managing Director, Gattefossé India.



# New excipient: Emulfree® Duo, innovative texture provider





Watch the video

Gattefossé expands its range of high quality, functional excipients for skin delivery with Emulfree® Duo, a stabilizing agent designed for topical drug formulations.

#### What is Emulfree® Duo used for?

<u>Emulfree® Duo</u> is a ready-to-use system designed to stabilize the oil phase in bigels by ensuring fine and homogeneous dispersions within the aqueous phase.

#### What is a bi-gel?

A bi-gel consists of an intimate mixture between aqueous and oily gels. Although bi-gels are known in the cosmetic and food industries, it is emerging as an innovative pharmaceutical dosage form.

Due to its dual nature, bi-gels provide advantages such as cooling and moisturizing effects, improved spreadability, and enhanced drug absorption through the skin. It is suitable for both lipophilic and hydrophilic drugs.

#### How different from an emulsion is it?

Bi-gels obtained with Emulfree® Duo look like emulsions but they are not as they do not contain emulsifier. Macroscopically, bi-gels can range from light sprayable lotions to rich creams, and microscopically their dispersions are fine and homogenous. And this happens with a PEG-free stabilizing agent.



"At Gattefossé, fostering innovation is in our genes and it is our role to provide new excipients that inspire our customers. With Emulfree® Duo we offer the pharmaceutical industry a bridge between appealing texture and efficient skin delivery associated in a bi-gel" says Héloïse Imbault, Global Head of Marketing, Pharmaceuticals

"Formulating topical dosage forms with Emulfree® Duo is both exciting yet so simple! Formulations are processed entirely at room temperature and result in a wide range of textures, from light lotions to rich creams" explains Elise Dauphin-Chanard, Application Lab Manager

