



CORPORATE PRESENTATION

PRES-CARIL-002-01-EN / FEBRUARY 2020

ACTIVITIES

Laboratoires Carilène are specialized in **Research & Development of Medical Devices for dermatological purposes.**

Les Laboratoires Carilène are « **manufacturer** » of **Glycerol Oxidized Triesters** from essential vegetable fatty acids whose production site is located in Montesson in France.

These peroxidized oils are intended for the **Cosmetic industry** and for the **Medical Devices** activity field.

Laboratoires Carilène are also « manufacturers » of Medical Devices within the meaning of the Medical Device Regulations, the productions of which are subcontracted as “Full-service” to manufacturers located in France.

The main commitment of Laboratoires Carilène is to provide **quality health products with a high degree of security that meet the requirements and expectations of customers and patients.**

Leader in the field of **Medical Devices for dermatological purposes**, Laboratoires Carilène ensure a global mastery of the stages from the design to the marketing of MDs whose post-marketing follow-up is also managed within the organization.

STATUS

Les Laboratoires Carilène, was created in 1982.
President & Founder : **Monsieur Stéphane Desjonquères**

ORIGIN - NATURAL PROCESS

From the Chaulmoogra oil that the Hindu peasants grew old in the sun, the story of a discovery....

As everyone of us knows, observing natural medicine, often oriental, is responsible for at least one in five health products ...

In the 1950s, Professor Baranger, member of the research team of the Institut Pasteur, engaged in the observation of natural medicines, traveled to India, in search of Chaulmoogra oils which he had heard said to have healing properties on ulcers caused by leprosy.

Professor Baranger discovers that these oils were exposed to the sun and air for more than twenty years before being used to treat leprosy wounds.

This « natural » process of vegetable oils by oxygenation due to atmospheric exposure as well as to sun rays (UV) brought about a fundamental change in the molecular structure of oils, thus transforming them into a fatty substance whose therapeutic properties were undeniable.



ORIGIN - INDUSTRIAL PROCESS

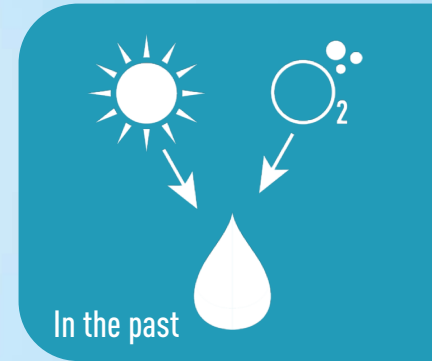
The result of the research

Professor Baranger had to share this discovery.

He was also a remarkable chemist. He then initiated a research program with the aim of replacing this long natural process with an accelerated industrial method.

The fruit of his research culminates in an industrial process making it possible to obtain oils with the therapeutic virtues expected in just a few days....

It was therefore Professor Baranger who normalized the production of this active oxygen at the heart of the chemical structures of fatty substances and who found its applications, before bequeathing his know-how, in 1982, to Stéphane Desjonquères, Founder of the Laboratoires Carilène.



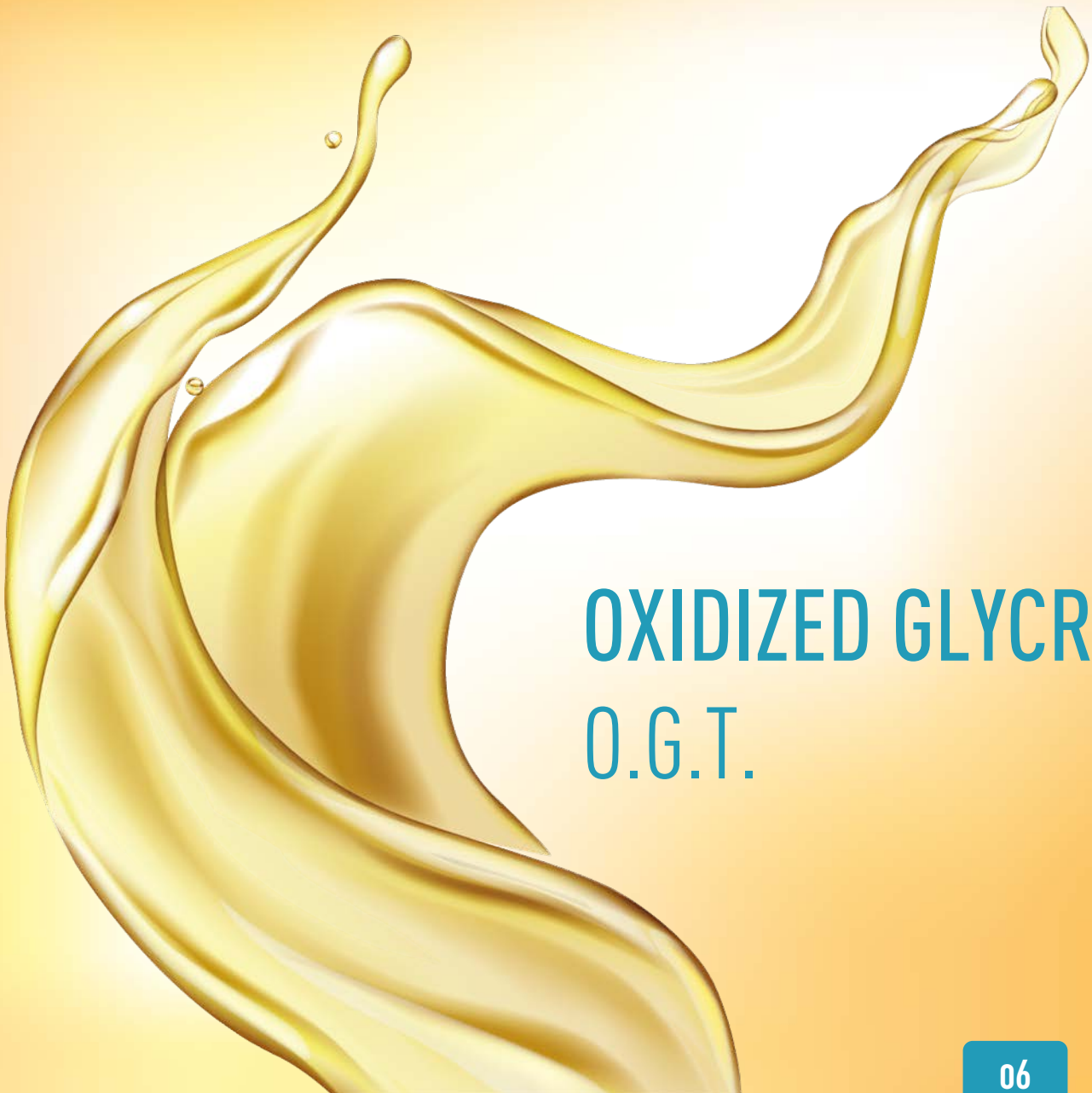
Since their creation in 1982, Laboratoires Carilène have exploited the therapeutic properties, by mechanical action, of Oxidized Glycerol Triester in various indications.

HISTORICAL

For more than 35 years, the R&D department of Laboratoires Carilène has explored many fields of application of these peroxidized oils in topical application in galenical forms such as cream, gel, oily solution, etc.

The tolerance and performance of each new product developed by Laboratoires Carilène is demonstrated by carrying out biological evaluation tests and by clinical investigations in accordance with European regulatory requirements.

Product patents or application patents protect all the references in the range of products developed and put on the market by Laboratoires Carilène.



OXIDIZED GLYCROL TRIESTERS O.G.T.

O.G.T. :

Oxidized Glycerol Triesters obtained from the oxidation of vegetable oils

OXIDIZED GLYCEROL TRIESTERS

Laboratoires Carilène have implemented the specific process of controlled oxidation of vegetable oils and thus manufacture **Oxidized Glycerol Triesters**. OGTs are produced in the industrial unit of Laboratoires Carilène, located in Montesson (Ile de France) whose **site is ISO 13485: 2016 certified**.

Laboratoires Carilène have control of the industrial process for manufacturing OGTs. Oxidation is controlled throughout production by an « in-process control » by measuring the peroxide index.

At the beginning of the 1980s, Laboratoires Carilène were the pioneers in the development of the industrialization of the controlled oxidation process of vegetable oils.

From demonstrated biomechanical properties, **OGTs (Oxidized Glycerol Triesters)**, by local application, open up **a wide therapeutic universe**. Thus, OGT, when applied locally, induce the formation of a **protective lipid film** on the skin or mucous membranes with a demonstrated **alleviating action**.

DEMONSTRATION OF CLINICAL BENEFITS

Clinical studies undertaken by Laboratoires Carilène demonstrate the performance of products based on Oxidized Glycerol Triesters compared to comparators, placebo or reference product.

The clinical benefits provided by the Oxidized Glycerol Triesters allow symptomatology **to be quickly and significantly improved** in indications such as dry mouth (Xerostomia), genital herpes, labial herpes, breast pain (Mastodynia), gingival pain, mouth ulcers, canker sores, supportive rash and pressure ulcer prevention, cheilitis...

The Oxidized Glycerol Triesters **restore the hydrolipidic protective film and accelerate the renewal of the underlying cells**, limiting water loss.

The main effects of Oxidized Glycerol Triesters are:

- Lubricant
- Adhesive by the formation of a lipid film limiting water loss and restoring the viscoelasticity of the mucous membranes
- Protector against local aggressions

IDENTIFICATION OF SUBSTANCES

according to Regulation (EC) n° 1907/2006 (REACH), modified by Regulation (EC) n° 2015/830

INCI Name :	OXIDIZED CORN OIL
Property name :	Peroxidized Corn Oil - Deodorized Peroxidized Corn Oil – Epaline 100 – Epaline DM – OGT
CAS number :	223705-62-2
EC number :	946-247-6
Use :	Industrial Ingredient for Medical Device Ingredient for Cosmetic Product

REACH File deposited with ECHA under the decision number: 01-2120745900-56-0000

SPECIFICATION OF SUBSTANCES

Organoleptic characters:

Appearance: **oily liquid**

Odor: **neutral**

Color: **Yellow to golden yellow**

Solubilities:

Insoluble in water

Practically insoluble in alcohol

Miscible with petroleum ether (50 ° -70 °)

Viscosity at: **10 - 50 cSt**

Acid index: **<0,5**

Epaline 100 peroxide index: **from 50 to 150 mEq/kg**

Epaline DM peroxide index: **de 50 à 90 mEq/kg**

Composition of fatty acids: Eph currently applicable

Fatty acid C16:	≤ 0.6%
Palmitic acid C16:	8.6 – 16.5%
Stearic acid:	≤ 3.3%
Oleic acid C18:1	20.0 – 42.2%
Linoleic acid C18:2	39.4 – 65.6%
Linolenic acid C18:3	0.5 – 1.5%
Peanut acid C20	≤ 0.8%
Eicosenoic acid C20:1	≤ 0.5%
Behenic acid C22	≤ 0.5%
Other fatty acids	≤ 0.5%

STABILITIES

Stability studies have been carried out internally by Laboratoires Carilène in order to demonstrate the stability of peroxidized oils throughout their life cycle.

The peroxidized oils Epaline 100 and Epaline DM have a shelf life of 36 months.

Long-term studies under specific storage conditions have been carried out.

The main objective was to demonstrate the conformity of the peroxide indicator claimed over 36 months in the different types of primary containers.

MODE OF ACTION

Oxidized Glycerol Triester, OGT, are vegetable oils stabilized by hyper-oxygenation.

A new therapeutic universe:

Based on proven biomechanical properties, the Oxidized Glycerol Triesters (OGT), by local application, open a wide therapeutic universe.

Thus, OGTs, applied locally, induce the formation of a protective lipid film on the skin or mucous membranes, with a proven calming effect and stimulation of the cutaneous microcirculation by massage.