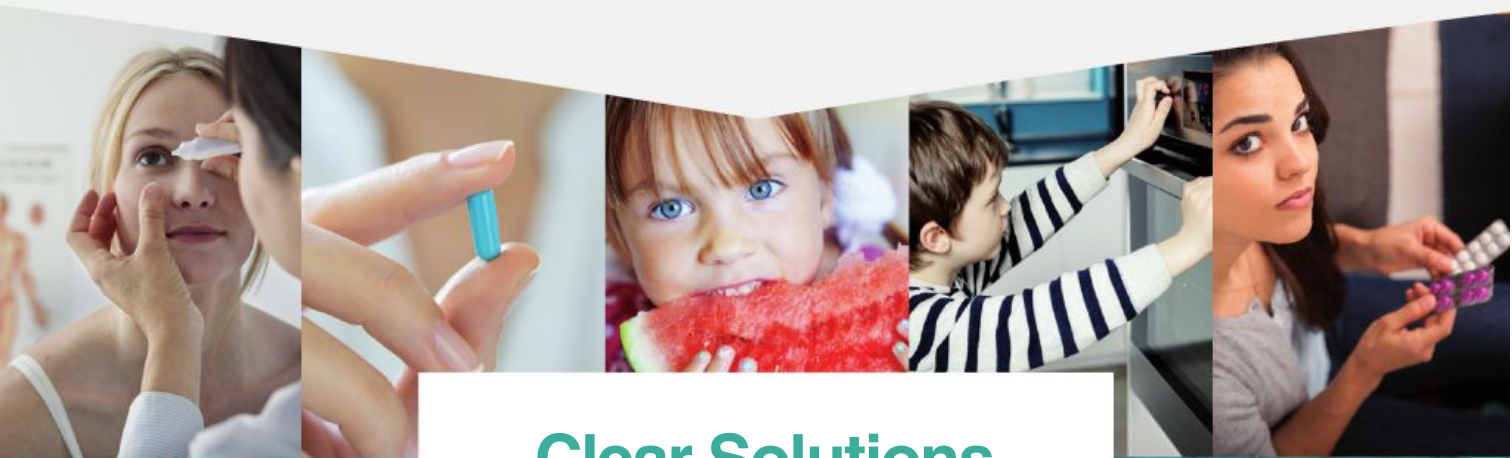




CLEAR SOLUTIONS FOR A SMARTER LIFE



**Clear Solutions  
for a Smarter Life**

PRESS KIT  
CPhI Japan 2017 - April 2017

DIGITAL BOOKLET

## PRESS RELEASE

### PYLOTE DEVELOPS ITS COMMERCIAL PRESENCE IN JAPAN

**Tokyo/Toulouse, 12 April 2017** – Pylote, the new player in the green mineral chemical sector, participates at CPhI Japan in Tokyo on April 2017 to promote its breakthrough proprietary innovations providing antimicrobial protection in the pharmaceutical and cosmetics industries.

During this most comprehensive pharma event, which brings together more than 20,000 pharma industry professionals from 100+ countries, Loïc Marchin, CEO of Pylote, will hold a conference on April 20 at 11:00 am on the beneficial effects of its breakthrough proprietary innovation PYCLEAR™ PROTECTION providing antimicrobial protection in many pharmaceutical and cosmetics specialties.


This presence of Pylote at CPhI Japan is part of its 2017 commercial development in Japan with the active and concrete support of *Business France*, the French national agency supporting the international development of the French economy and responsible for fostering export growth by French businesses.


*“Pylote is today able to provide in the Japan pharmaceutical & cosmetic markets its proprietary solutions with complete statutory compliance such as Japanese, European and US pharmacopeias or Food Contact. Our solutions are totally ready to use and adaptable to every type of packaging, manufacturer & contents.”* commented Loïc Marchin, CEO of Pylote

In the recent months, Pylote has conducted in Europe a whole set of agreements with key major players in packaging solutions, such as Argo in October 2016, for mutual referencing to provide innovative packaging solutions for greener, cleaner and safer unpreserved pharmaceutical specialties & ophthalmic products. Pylote intends to set such type of partnerships with major key players on these industries in Japan.

Today, Pylote, with its exclusive manufacturing process, has more than 200 partnerships with industry worldwide and more than 50 to provide CE marking & AMM products

#### Additional information

 PYCLEAR™ PROTECTION is a major technological innovation that replaces antimicrobial preservatives used in many pharmaceutical and cosmetic specialties for which no change is needed in packaging nor in existing manufacturing processes. PYCLEAR™ PROTECTION provides an ideal “eco-friendly” answer to the regulatory authorities’ requirements which are looking to remove the use of preservatives. Developed in full compliance with regulations, this solution is highly suited for multi-dose eye drop flasks, nasal spray used preparations, and also for skin care cosmetic products.

 In 2016, Pylote has received in Europe three major awards for its innovation PYCLEAR™ PROTECTION: the Pharmapack Award 2016 in the Best Exhibitor Innovation category for “Patient Protection & Cost-Efficiency in February 2016, the prize in the Excellence in Pharma-Packaging category at CPhI Europe Barcelona in October 2016, and the French Packaging Award 2016 in the Small & Medium Enterprises category in November 2016.

**ABOUT PYLOTE** - Founded in 2009, Pylote is committed to green industrial chemistry in the mineral and ceramic chemical sector. Through the range of its efficient PYCLEAR™ solutions, Pylote conceives and develops innovative mineral microspheres to sell solutions which can be integrated into numerous consumer products. Pylote’s solutions have a major competitive advantage as they make the end products smarter, by giving new and specific advantages and attributes to materials, with no change to the existing manufacturing process. Pylote helps their clients, who are present in pharmaceutical, cosmetic, luxury, food or industrial markets, to propose end consumers with more eco-friendly products that are greener, cleaner and safer. For more information about Pylote [www.pylote.com](http://www.pylote.com)

#### PR contacts:

**H2D Advisory** - Jean-Christophe Huertas - Tel: +33 6 16 99 47 05 - [jean-christophe.huertas@h2dadvisory.com](mailto:jean-christophe.huertas@h2dadvisory.com)

**Business France** – Kaori Suenaga – Tel: + 81(0)3 57 98 61 28 – [kaori.suenaga@businessfrance.fr](mailto:kaori.suenaga@businessfrance.fr)



**SMART & INNOVATIVE**

An exclusive process methodology using water as the core of the chemical reaction.

**Deliver greener,  
cleaner, safer  
consumer products**



**CLEAR & GREEN**

A green and mineral Pulverised Pyrolysis technology which reduces the environmental impact of the manufacturing process



Pylote is committed to green chemistry in the mineral and ceramic chemical sector.

Pylote helps their clients, who are present in pharmaceutical, cosmetic, luxury, food or

“ **Pylote unites scientific and technical innovation to make a difference to everyday life, and promotes the benefits of green, mineral chemistry.** ”

We conceive and develop innovative mineral microspheres to sell solutions which can be integrated into numerous consumer products without any change to the existing manufacturing process.

industrial markets, to propose to end-consumers more eco-friendly products, that are greener, cleaner and safer.

**Loïc Marchin** - CEO of Pylote

---

## AWARDS

---



BEST EXHIBITOR  
INNOVATION



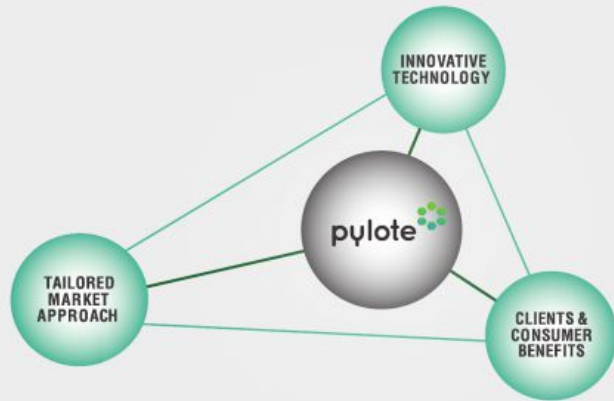
EXCELLENCE IN  
PHARMA-PACKAGING



PROPRIETARY ANTIMICROBIAL  
INNOVATIONS

# pylote

CLEAR SOLUTIONS FOR A SMARTER LIFE



## Innovation

- Unique green mineral microspheres
- Regulatory standard
- Final product benefits validation

## Intellectual property

- Exclusive proprietary manufacturing process
- 11+ patents and patents applications

## Technological solutions with market impact

- Integration into numerous consumer products
- No change to existing manufacturing process
- Cleaner, greener and safer final products

## Client partnership benefits

- 200+ ongoing partnerships with industry worldwide
- 50+ ongoing partnerships to provide CE marking and AMM products

Worldwide pioneer  
in green mineral  
microspheres

Cleantech & mineral  
Pyrolyse Pulvérisée™  
creating smart materials

Innovative technological  
solutions under  
pyclear™ portfolio

No environmental impact  
& value added benefits  
of the final products

Committed to Quality-  
Safety-Environment

# Market solutions

Click on the product to access the content

  
**PROTECTION**  
Preservative removing  
Packaging simplification



  
**DURATION**  
Extends utilization benefits  
Prolongs product's effects



  
**PRESERVATION**  
Prolongs shelf life  
Food waste reduction



  
**AUTHENTICATION**  
Authenticity verification - Applied to final  
products with no design adaptation



  
**ENERGY**  
Energy consumption reduction







## Patient protection - Better cost of goods



**Medicines**



**Cosmetics**

- Remove preservatives
- Microbial protection
- 100% mineral:  
nano free & silver free
- Simplifies packaging
- No change in use,  
design, manufacturing,  
packaging & content



Eye dropper



Nasal spray



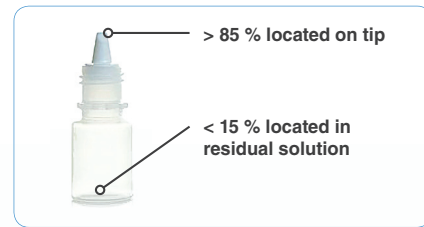
Skin care



## Context & challenges

- **Antimicrobial preservatives: side effects** for patients
- Market/regulatory pressure: **remove preservatives**, lowering preservative volume/number
- **Public perception:** parabens, nanosilver, bacterio-resistance, microbiome challenges

### Contamination localization<sup>(1)</sup>:



(1) Nentwich et al., Br. J. Ophthalmol. 2007. 91 : 1265-8.

### PYCLEAR™ PROTECTION ANSWERS

- **Remove antimicrobial preservatives from formula**
- **Protect content & each delivered doses until the consumer**
  - **No change in consumers buy-act nor usage**
    - **No packaging / process modification**
    - **Nano-free, Silver-free, fully recyclable**
  - **Regulatory / stability / safety compliance**

# Agreed Supply chain

Microspheres  
integration in  
plastic

Conventional  
Plastics  
transformation  
process

Sterilization/  
Filling/...

Regulatory files

Pylote Added  
Final products



## Microspheres production

- One-step “cleantech” patented process: Pyrolyse pulvérisée®
- Improved 100 % mineral microspheres (nano-free, silver-free)
- Food contact agreement, Ph. Eur., USP compliance, Ecocert

## Management by Pylote’s Experts

- No change to the existing manufacturing process
- Supply chain evaluation/agreement
- Specific products Data acquisition for regulatory files

## Pyclear Protection benefits

- More eco-friendly products : cleaner, greener, safer
- No change in use, design, manufacturing & content



# Proof of concept

## Dispenser contamination protection

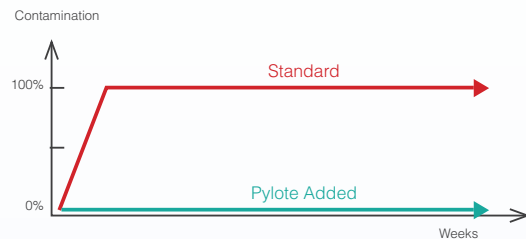
Antimicrobial activity (JIS Z 2801 : 2010)

Strains	Log reductions / cm <sup>2</sup>
<i>Escherichia coli</i> CIP 53126	5.2
<i>Staphylococcus aureus</i> CIP 4.83	> 3.1
<i>Pseudomonas aeruginosa</i> CIP 82118	4.4
<i>Streptococcus pyogenes</i> CIP 5641T	2.9
<i>Herpes simplex virus type 1</i> (HSV-1)	2.2
<i>Influenzavirus A</i> (H1N1)	2.6

## Dose and content protection

In-use tests performed in worst conditions: Full protection

(dispenser contamination 2 times/day by *P. aeruginosa*, *S. aureus*, *E. coli*, *C. albicans*, *A. brasiliensis*).



## Reglementary analysis

- Food contact agreement, Ph. Eur., USP compliance, Ecocert
- Complete antimicrobial protection until the consumers
- Formulation stability (no physico-chemical changes)
- Leachables and extractables within limit



## Simplified regulatory approach

- **Only 1 modification to the entire process:** adding microspheres to your actual plastic resin (already in your regulatory file)
- **Data for your specific formulations are generated during Pre-Industrial Contract by independent and certified labs**
- **Microspheres composition was referenced in the monographs** (Eu.Ph., USP,...), so already in compliance
- **Easy to understand specifications and drawings - no technical knowledge required**
- **Microspheres are Ecocert certified**
- **Packagings remain fully recyclable**
- **We provide data concerning the microspheres and suppliers evaluation to complete your specifications**
- **Multi sourcing of your packaging**

## Business model opportunities

Case studies with Pylote Added ophthalmic products in 5 or 10mL classic plastic eye dropper. PYCLEAR™ PROTECTION allow a downgrade of your MD from 2b to 2a class for 2 mains reasons listed in the Pharmacopoeias:

- **Dropper volume limited to 10mL**
- **Treatment period limited to 4 weeks (you need an authorization to prolong)**



BREAKTHROUGH INNOVATION | REPLACES ANTIMICROBIAL PRESERVATIVES <sup>(1)</sup>

• **Full consumers protection:**  
removes the use of preservatives and ensure  
clean & pure doses upon each application

• **Complete statutory compliance:**  
European Pharmacopoeia, USP, Food contact

• **Packaging simplification and economic benefits:**  
no changes in the manufacturing packaging process

• **Adaptable to every type of packaging,  
manufacturer and contents.**

Contact us

to transfer our innovative technology  
to your commercial product !

(1) **Accepted paper (2016):** "Unpreserved ophthalmic formula: PYCLEAR™ PROTECTION fully controlled risk of contamination with common 3-parts eye droppers".



pyclear   
DURATION

## Extends time-life effect & delivery



**Medicines**



**Food**



**Industry**

- Extends utilization benefits
- Reduces replacement frequency, material and transport requirements
- 100% mineral: nano free & silver free
- Allows drug delivery with release control



Pills



Implants & patch



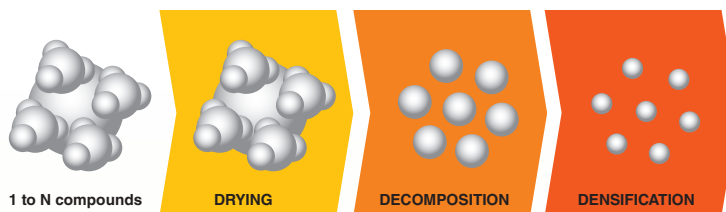
Biological medicines





## Pyrolyse pulvérisée®

Improved ceramic microspheres obtained via one step « cleantech » manufacturing process: Pyrolyse pulvérisée®

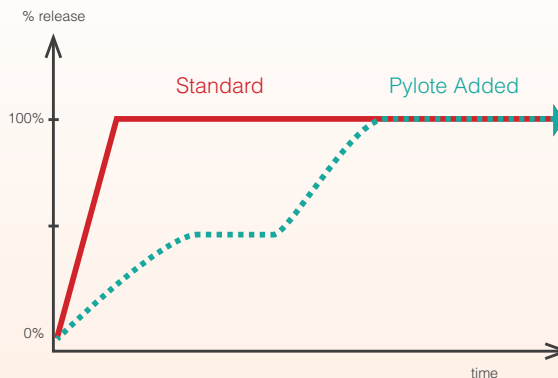


ONE STEP «CLEANTECH» MANUFACTURING PROCESS

## Delivery control

### Desired release profile can be achieved

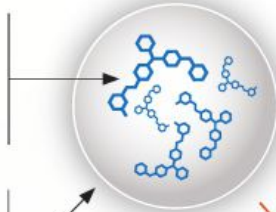
- Uniform size, spherical shape: improve delivery to specific target site
- High sphericity: more controlled integration and release
- A bioceramic matrix: chemical protection and biocompatible ingredients
- Fully controlled release with different kinds of molecule/API
- Tailored and sequential drug release kinetics with specific microspheres porosity



## Sealed microspheres loading dyes - stationary applications -

- All colors available
- Food, Drug, and Cosmetic grade dyes (ex Acid Dye)

- Core and Shell
  - 100% mineral
  - Biocompatible
  - FDA compliance
  - Nano-free



- Integrable into organic and water-based ink
- Waterproof to organic solvent and water
- Microspheres protect Dye from chemical incompatibilities and degradation
- Pylote greentech micro-encapsulation Patented process
- Dense colored (<math><5\text{m}^2/\text{g}</math>)
- Ultra low leakage (<math><1\%</math>)



## - Benefits -

---

### **Universal color:**

Dye+Microspheres become compatible with all chemistry inks

---

### **Scale effect:**

Only 1 dye reference for all your product

---

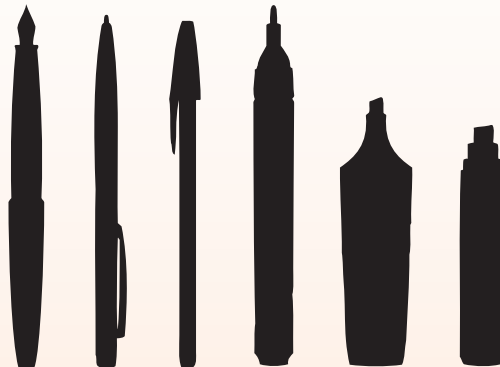
### **Economic benefits:**

Manage only 1 reference for all your product

---

### **Regulatory:**

Dyes referenced in eco-friendly list





CLEAR SOLUTIONS FOR A SMARTER LIFE

22 avenue de la Mouyssaguère  
31280 DREMIL LAFAGE - France

Tél : +33 (0)5.31.61.66.65  
contact@pylote.com

[www.pylote.com](http://www.pylote.com)

Press Contact : Jean-Christophe Huertas - H2D Advisory  
jean-christophe.huertas@h2dadvisory.com / + 33 6 1699 4705