

HELM PORTUGAL

# Pharma Ingredients & Materials Europe





# Octenidine Dihydrochloride

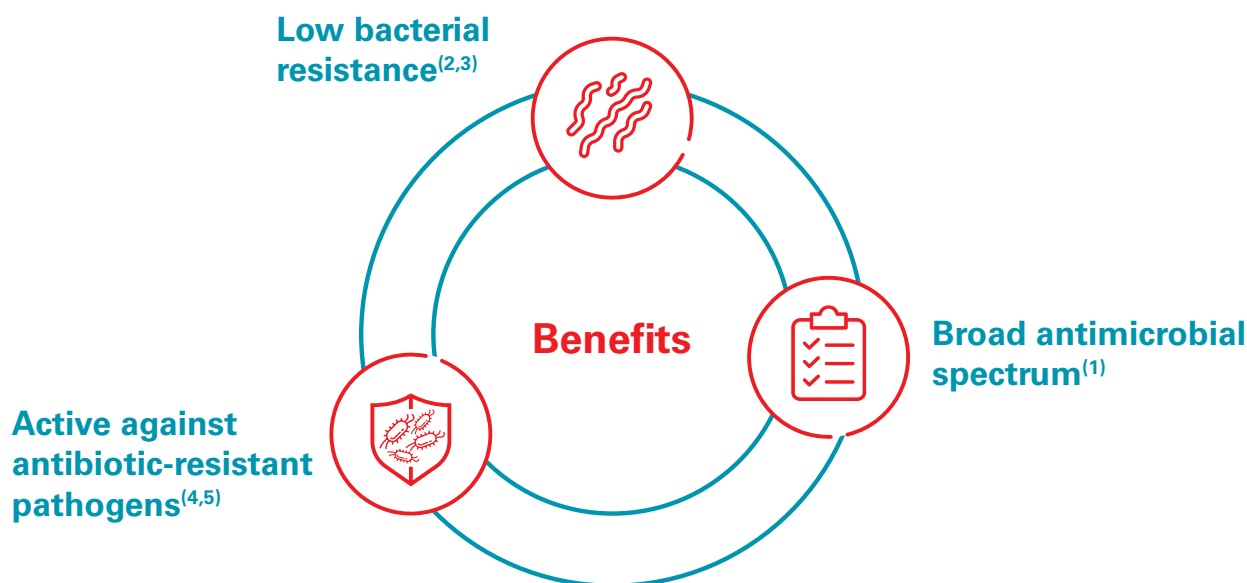
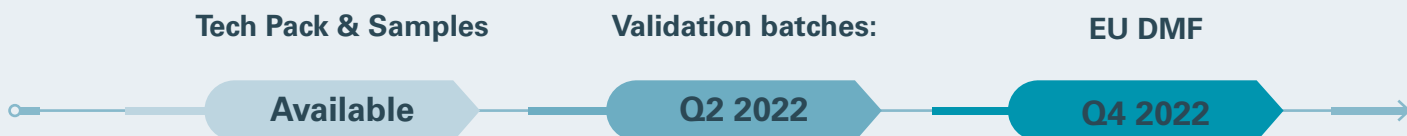
## HELM latest antiseptic API

### How Octenidine Works<sup>(1)</sup>

Octenidine is a cationic, surface-active substance, able to bind to microbial cell envelopes, disrupting cell membrane and microcellular metabolism, ultimately leading to cell death.

Octenidine has a broad antimicrobial spectrum against Gram-positive and Gram-negative bacteria and fungi, including *S. epidermidis*, *S. aureus*, *P. mirabilis*, *S. pyogenes*, *K. pneumoniae*, *E. coli*, *P. aeruginosa* and *C. albicans*.

### Project Timelines



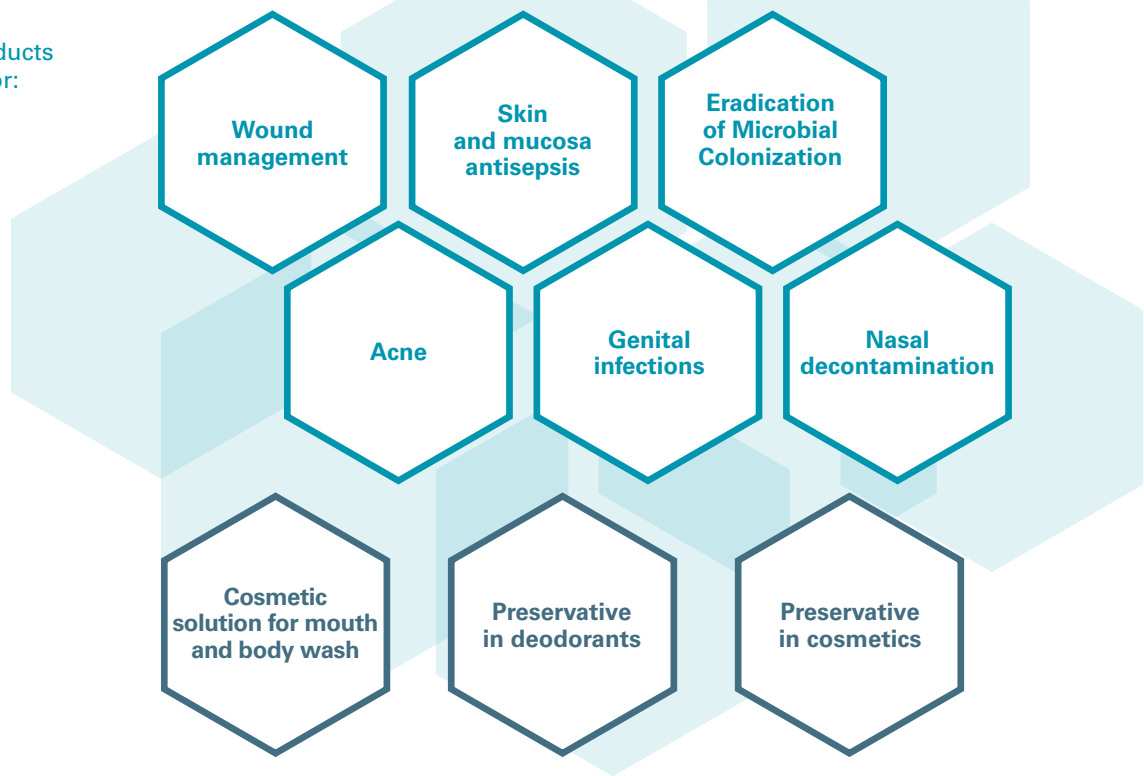
### Octenidine vs Chlorhexidine

In general, octenidine has a higher antiseptic activity than chlorhexidine. Furthermore, the concentration of octenidine necessary to achieve complete inactivation of bacteria and yeasts is much lower (approx. 10-fold) than for chlorhexidine.<sup>(6)</sup>

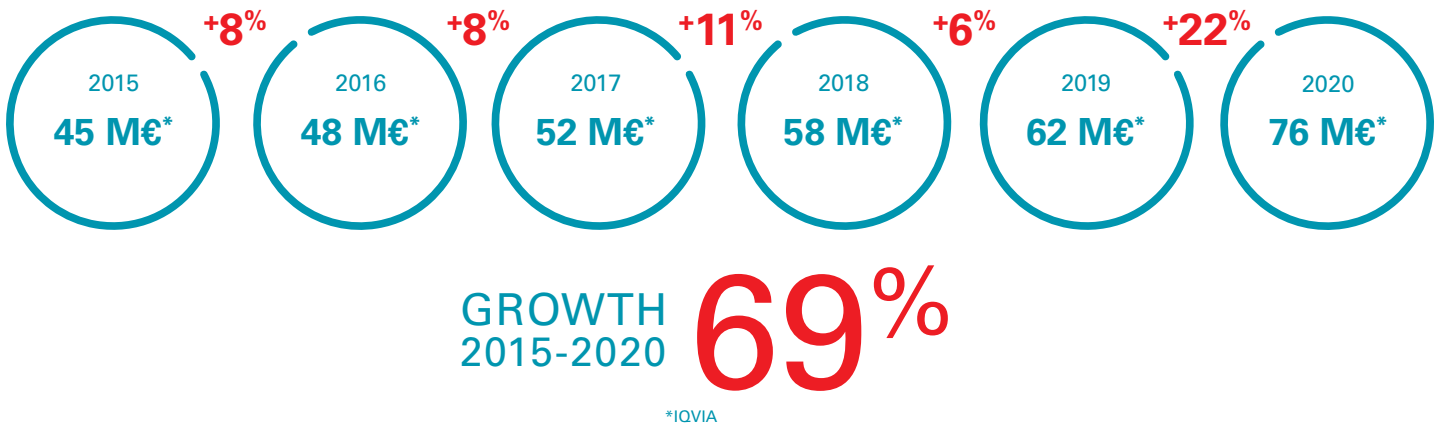
## Applications

### PHARMA

- Medicinal products applications for:



## FDF Worldwide market size and growth



Developed together with **Lebsa**

EU DMF available in Q4 2022



Want to know more about Octenidine? CONTACT

**Jovani Valdovinos**  
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(1): Hubner N.-O., et al. Octenidine dihydrochloride: A new topical antimicrobial for local treatment of skin, mucous membranes and wounds. *Skin Pharmacol Physiol.* 2010;23(5):244-58. doi: 10.1159/000314699 (2): Wand ME., et al. SmvA is an important efflux pump for cationic biocides in *Klebsiella pneumoniae* and other Enterobacteriaceae. *Sci Rep.* 2019 Feb 4;9(1):1344. (3): Chan MKL., et al. Development of a real-time assay to determine the frequency of qac genes in methicillin resistant *Staphylococcus aureus*. *J Microbiol Methods.* 2018 Oct;153:133-138. (4): Alvarez-Marin R., et al. Antimicrobial activity of octenidine against multidrug-resistant Gram-negative pathogens. *Eur J Clin Microbiol Infect Dis.* 2017 Dec;36(12):2379-2383. (5): Conceição T., et al. Efficacy of octenidine against antibiotic-resistant *Staphylococcus aureus* epidemic clones. *J Antimicrob Chemother.* 2016 Oct;71(10):2991-4. (6): Koburger T., et al. Standardized comparison of antiseptic efficacy of triclosan, PVP-iodine, octenidine dihydrochloride, polyhexanide and chlorhexidine digluconate; *J Antimicrob Chemother.* 2010 Aug;65(8):1712-9. doi: 10.1093/jac/dkq212.





# API Hexetidine

**Leaping** . Taking your  
API further

## HELM FROM DISTRIBUTOR TO MANUFACTURER

- API HEXETIDINE
- MANUFACTURED BY HELM IN EUROPE
- EU DMF PLANNED TO BE AVAILABLE IN Q2 2023

### Applications

Anti-infective and Antiseptic  
for local oral treatment:



- Alimentary Tract and Metabolism
- Stomatological Preparations

**HELM  
FROM DISTRIBUTOR  
TO MANUFACTURER**

Joana Tavares

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# Cannabidiol (CBD)

Synthetic API pharma grade

**DMF OPEN PART AVAILABLE**

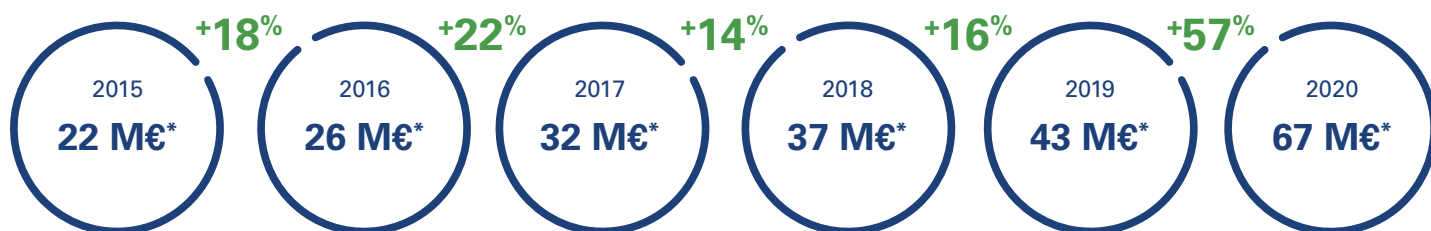


Our manufacturer is certified by FDA & DEA

Batch size 50 KG

Annual Capacity 7200 KG

## FDF Worldwide market size and growth



GROWTH 2015-2020 **197%**

\*IQVIA

### HELM

is one of the world's major independent chemicals marketing enterprises with 120 years of history and more than 100 subsidiaries, sales offices, and participations in over 30 countries.



**Want to know more about Cannabidiol? CONTACT**

**Jovani Valdovinos**

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# Vitamin CEP grade

15-days of lead time

**Vitamin C, also known as Ascorbic Acid, is an essential micronutrient. Humans lack the ability to generate endogenous vitamin C and are thereby completely dependent on dietary intake.<sup>(1)</sup>**

Vitamin C plays an important role in numerous physiological processes in the human body:

Immune function and maintenance of redox balance.<sup>(1-2)</sup>

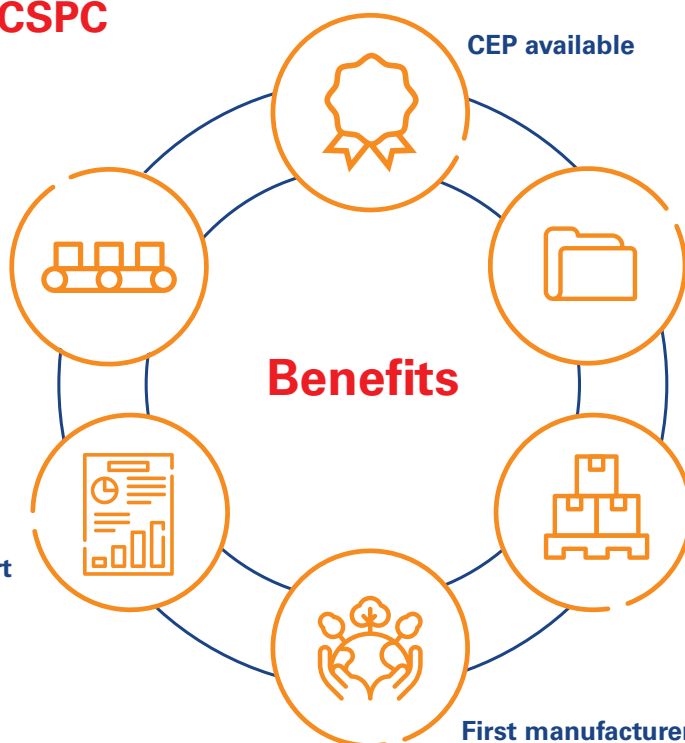
Wound healing, repair and maintenance of cartilage, bones and teeth.<sup>(3,4,5)</sup>

Enzyme cofactor and iron metabolism modulator.<sup>(6,7,8)</sup>

## Exclusive distribution agreement with CSPC

Largest ascorbic acid manufacturer in the world (60000 MT/year)

Available audit report



CEP available

Dedicated team of experts that will give you full technical support

Stock in Europe

First manufacturer to implement the latest environmental policy standards



**Multiple applications:  
pharmaceutical, cosmetic  
and nutritional**

**Flexibility in meeting your  
requirements (different PSD\*  
100, 325, mesh and crystalline)**

**Shelf life of 24 or 36 months  
depending on the PSD\***

**Standard: USP/EP/  
BP/JP/FCC/E300/CP**

**Packaging size:  
15, 25, 500 and 1000 Kg**

**Packing: carton  
and polyethylene bag**

\*Particle Size Distribution

## Tired of supply chain disruption and delivery delays?

**Stock in Portugal with  
15-days of lead time  
to European customers.**

OTIF\* OF  
**97%**  
IN ALL ORDERS  
IN 2020

\*On-Time In-Full

Despite the logistics and production  
output challenges caused by COVID-19.



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**Want to know more about Vitamin C? CONTACT**

**Jovani Valdovinos**

[ljvaldovinos@helmportugal.com](mailto:ljvaldovinos@helmportugal.com)

(1) Carr AC, Maggini S. Vitamin C and Immune Function. *Nutrients*. 2017;9(11) (2) Kazmierczak-Baranska J, Boguszewska K, Adamus-Grabicka A, Karwowski BT. Two Faces of Vitamin C - Antioxidative and Pro-Oxidative Agent. *Nutrients*. 2020;12(5). (3) Moores J., et al. Vitamin C: a wound healing perspective. *Br J Community Nurs*. 2013 Dec;Suppl:S6, S8-11 (4) Pullar JM., et al. The Roles of Vitamin C in Skin Health. *Nutrients*. 2017 Aug 12;9(8):866 (5) Aghajanian P., et al. The Roles and Mechanisms of Actions of Vitamin C in Bone: New Developments. *J Bone Miner Res*. 2015 Nov;30(11):1945-55 (6) Padayatty J., et al. Vitamin C physiology: the known and the unknown and Goldilocks. *Oral Dis*. 2016 Sep; 22(6): 463-493. (7) Abdullah M, Jamil RT, Attia FN. Vitamin C (Ascorbic Acid). *StatPearls*. Treasure Island (FL)2021. (8) Lane DJ, Richardson DR. The active role of vitamin C in mammalian iron metabolism: much more than just enhanced iron absorption! *Free Radic Biol Med*. 2014;75:69-83.

# Heparin Sodium CEP grade

## An essential anticoagulant

- Animal-tissue derived molecule, extracted mainly from the porcine intestinal mucosa.
- Anticoagulant effects proven over 100 years.<sup>(1)</sup>



**MOST USED  
IN THE WORLD**



**ACTIVE SUBSTANCE OF THE MOST USED  
ANTICOAGULANT AND ANTITHROMBOTIC  
DRUGS IN THE WORLD.<sup>(1,2)</sup>**

## Applications

**Antithrombotic  
medicinal products**

**Anti-atherosclerotic  
medicinal products**

**Medicinal products  
for hemorrhoids  
treatment**

**Topical medicinal  
products for ulcer  
treatment**

**Anticoagulant  
medicinal products**

**Anticoagulant  
coating for medical  
devices**

**Medicinal products for  
wound management**

## Porcine heparin vs Bovine heparin

- Porcine heparin has greater anticoagulant and antiprotease activities than bovine heparin.<sup>(3)</sup>

**HELM'S HEPARIN IS EXTRACTED  
FROM THE PORCINE INTESTINAL  
MUCOSA**



## Competitive edges



### SAFETY

HELM works with authorized farms that are properly inspected and cleared by veterinaries before use.



### FULL TRACEABILITY

HELM ensures safety, quality and full traceability along the whole supply chain of Heparin. Our processes are designed to minimize any possibility of biological risk.



### FULL TECHNICAL SUPPORT

Technical experts dedicated to Heparin and technical documentation ready to be sent.



### EXPERTISE

HELM provides its partners with market intelligence about future price development.

## Key characteristics

1. Shelf life of 36 months
2. Package of 5kg and 10kg
3. Batch sizes of 25000 – 28000 mega



CEP



USDMF

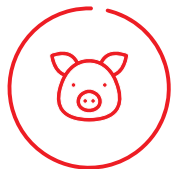


WRITTEN CONFIRMATION



AUDIT REPORT AVAILABLE

## Supply chain



**PIG FARMER**  
Healthy pigs that are inspected by vets and come only from authorized farms



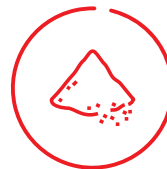
**SLAUGHTER HOUSE**  
The pig intestines come from government-inspected slaughterhouses



**INTESTINES**  
Fresh intestines are inspected



**MUCOSA**  
The mucosa is separated from the rest of the intestine



**CRUDE HEPARIN API Intermediate**



**HEPARIN SODIUM**  
Highest quality API fully compliant with the most demanding international quality standards

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Want to know more about Heparin? CONTACT

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# API PRODUCT LIST

API	DMF Compliance	CEP	Audit report
ASCORBIC ACID	EP	√	√
AZITHROMYCIN DIHYDRATE	EP and USP	√	√
BENFOTIAMINE	EP	X*	Planned
CAFFEINE	EP	√	√
CANNABIDIOL	EP and USP	X*	To be scheduled
CARBOCISTEINE	EP	√	√
CLARITHROMYCIN	EP	√	√
CYANOCOBALAMIN	EP	√	√
DICLOFENAC SODIUM	EP	√	To be scheduled
DIMETINDENE MALEATE	EP	√	√
HEPARIN SODIUM	EP	√	√
IBUPROFEN	EP	√	√
MUPIROCIN CALCIUM AND BASE	EP	X**	To be scheduled
OCTENIDINE DIHYDROCHLORIDE	EP	X*	To be scheduled
SODIUM ASCORBATE	EP	√	To be scheduled

\* No EP monograph available \*\* CEP procedure ongoing

**Leaping** ■ Taking your  
API further

**HELM Partnership Program for  
API co-developments with strategic partners**