

CITROLEDUM® FAMILY

STICK

after-insect bites lenitive stick – without ammonia



SCIENTIFIC AND TECHNICAL DOSSIER

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TECHNICAL PROFILE

1. Product Information

Product (Trade) name (as used in the country of origin)	CITROLEDUM®FAMILY STICK
Ingredients	Aqua, Aloe Barbadensis Leaf Juice, Propylene glycol, PEG-40 Hydrogenated Castor Oil, Alcohol Denat., Chamomilla Recutita Flower Extract, Hydroxyethylcellulose, Malva Sylvestris Leaf Extract, Calendula Officinalis Flower Extract, Parfum, Imidazolidinyl Urea, Phenoxyethanol, Menthol, Methylparaben, Ethylparaben, Isopropyl Alcohol, Sodium Hyaluronate, Propylparaben, Cellulose.
Active Substance(s) and origin	Aloe Barbadensis, EXTRA EU (Mexico) Chamomilla, EU Malva Sylvestris, EU (Albany) Calendula Officinalis, EXTRA EU (Egypt)
Dosage form	Lotion stick
Route of Administration	Dermal route
Container, closure and administrative device	Pen stick
Pack size	10 ml
License/ Marketing authorization holder (name, address & country)	Phyto Garda srl, Via San Isidoro, 4 – Loc. Vanzelle 37010 Rivoli Veronese (VR) - Italy
Number and date of first marketing authorization/renewal	2003/2016

CERTIFICATE OF ANALYSIS

Please see following attachment (n.1)

GMP

Please see following attachment (n.2)

Certificate of Analysis

Article: **Dopopuntura penna naturale**

Batch n: 20002

Production date: 07/01/2020

PAO 12 M

TEST test method	Low limit	Up limit	Test result	Complies (C-NC)
Appearance	Gel		Gel	C
Colour	Pale Yellow	Light Brown	Light Brown	C
Odour	Characteristic		Characteristic	C
Density (g/ml)	0.980	1.000	1.00	C
pH	5.00	6.50	6.50	C
Viscosity (Brookfield RVT) mPas sec	3000	3500	3500	C
Total Aerobic Microbial Count (TAMC)		< 100 UFC/ml	< 100 UFC/ml	C
Total Combined Yeasts/Moulds Count (TYMC)		< 100 UFC/ml	< 100 UFC/ml	C

Complies codes:

- C (Conform/Complies)
- NC (Not Compliant)

Date 27/02/2020

Technical Manager

CoA

Article: : Dopopuntura Penna Naturale - Batch n 20002



IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N.
CERTIFICATE No.

6811/2

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

[Faded text, likely the name of the certified entity]

È CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / Quality Management System

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

EA: 12 - 29

Sviluppo, produzione e confezionamento per conto terzi di PMC, biocidi, cosmetici e dispositivi medici in forma liquida, semisolida, gel e crema. Produzione per conto terzi di salviette e bustine monodose. Commercializzazione di prodotti tricologici.

Development, production and packaging for third parties of PMC, biocides, cosmetics and medical devices in liquid, semi-solid, gel and cream form. Production for third parties of wet wipes and single dose sachets. Trading of trichological products.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.

For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

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ICIM S.p.A.

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SGQ N° 004 A

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CISQ is the Italian Federation of management system Certification Bodies.