

Report on the safety of the cosmetic product N°: **00001**

Product identification: Digital Brush_ Chlorhexidine 0,12%

by Quality Assurance Manager

Part A

Product identification: ECDB... DB DIGITAL BRUSH
Description: Digital Brush_Disposable gauze for teeth and mucosa soaked in Chlorhexidine 0,12%
Category: Products for tooth and mouth hygiene
Quantitative and qualitative composition of the product: See INCI enclosure.
Physical characteristics: Aspect: Solid, humidified Colour: White Odour: mild medicine odour Raw material: nonwoven fabric soaked in 3 ml of mixture prepared with the substances indicated in the INCI enclosure.
Microbiological Quality: the analysis of the product has pointed out the conformity of the microbiological quality.
Purity of the substances and mixture: the mixture doesn't show any trace of impurity or toxic compounds.
Traces of forbidden substances: not present.
Destination and Instructions for use: Teeth and mucosa oral hygiene. The pictures on the packaging show the correct steps to use the gauze. After opening the packaging, place your finger in the centre of the gauze (picture 1). Wrap the gauze around your finger (pictures 2-3-4). Run the gauze repeatedly on all the oral surface.

Image of the product



Place of application: Oral cavity

Extension of the surface of application: All the mouth: from the mucosa to the tooth surface, including tongue.

Applied quantity of product:

The size of the gauze is 14 x 19 cm and it is soaked in 3 ml mixture.

Duration and frequency of use:

It can be used daily. Recommended time 2 minutes following the instructions on the packaging.

It can be used several times a day, in case of moderate-serious gingival inflammation for about 15 days or until the complete remission of any inflammatory sign or symptom.

Normal or reasonably predictable ways of exposure:

Oral cavity: mucosa and teeth

Target population (or exposure):

All individuals except babies, for whom a version with physiological solution has been designed.

It is indicated in particular for individuals that suffer from gingival inflammation and induced plaque both localized and generalized.

Features and Advantages:

- Nonwoven fabric gauze: Gauze: viscose 65%, polyester 35%.

- 9,5 x 6,5 cm

- Pocket packaging, ideal for outdoor use

- The fabric of the gauze is soaked in a mixture with 0,12% of Chlorhexidine, a substance that is renowned for its antiseptic properties.

- Simply wrapping the gauze around your finger, you can make a light mechanical cleaning on the tooth surface and mucosa thus maintaining a good oral hygiene, as this action helps to prevent dental plaque.

- The product is easy to use, so it is ideal also for people with limited manual ability

- The product is disposable, which allows to maintain the functional characteristics of the product for the period indicated on the packaging.

- The external packaging is made up of a triple layer of sheets in order to maintain the product intact.

Warnings and contraindications:

Instructions for use on the label:

Name and address of the responsible company:

Micerium S.p.A. Via G. Marconi 16036 Avegno (GE)

Origin country:

The product has Italian origins

Weight and volume indications: (except for packages that contain less than 5 g or 5 ml of product)*: not indicated as the package contains 3 ml.

Date of minimum duration of the product (stocked in normal conditions):

5 years from production

Special precautions for use:

None

Lot number: present

*package with several pieces (please indicate only the number of pieces in the package).

Function of the product:

Disposable gauze for teeth and mucosa – close-at-hand sanitizer – a simple daily habit that helps to prevent dental plaque in the oral cavity. The pocket solution for a total oral hygiene, wherever you are! – Chlorhexidine has renowned antiseptic properties.

“**Ingredients**”: **OK** (for the ingredients listed on the package please see INCI).

Exposure to substances for the relevant toxicological thresholds: The mixture is not toxic.

Toxicological profile of the substances: The mixture is not toxic

Information about the material of the package: envelope/packaging: PE, Aluminium, PET.

Shelf life: 5 years

Storage: No special indication

Min and Max Temperatures in °C: -4° and 39°

Interruption at temperature: No

Transport: No special indication

Min and Max Temperatures in °C: -4° and 39°

Interruption at temperature: No

Possible maximum hours of transport: No special indication

Freezing resistance: No special indication

1. Conclusions of the assessment:

Micerium S.p.A. declares that the cosmetic product launched on the market is not dangerous for human health, if it is used in normal or reasonably predictable conditions, considering in particular the presentation under the directive n. 87/357/CEE, the labelling, the instructions for use.

2. Warnings and instructions for use on the label:

Micerium S.p.A. declares that the label respects what stated by the CE Regulation n.1223/2009.

3. Motives for the declarations of sections 1 and 2:

As one can deduce from the analysis of the product in this Safety Sheet and from the risk analysis of family 11 cosmetics, Micerium can confirm that the examined cosmetic product is not dangerous for human health and for the user's safe (in normal and reasonably predictable conditions of use). There isn't any problem related to:

- the substances used for the composition of the product
- the stability of the product
- the toxicity of the product
- the exposure to the product or to substances contained in the product
- the toxicity of the substances
- any serious undesired or undesirable effect

Approval by the Quality Manager of Micerium S.p.a.: Eugenio Miceli

Date: 18-12-2012

Signature:

Annex 1



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DIGITAL BRUSH CHLORHEXIDINE 0,12%

INCI related to the composition of the gauze dampened with Chlorhexidine 0,12%
Digital Brush

1.	Aqua	
2.	Sorbitol	Sweetener , bacteria that can cause caries don't metabolize it, it prevents the dehydration of the product.
3.	Alcohol Denat.	Preservative and Solubilizer
4.	Propylene Glycol	Solubilizer
5.	Laureth-9	Surfactant (Iron sequestrant). It sequesters the iron ions and prevents the tooth discolouring, a well-known contraindication of Chlorhexidine.
6.	Polysorbate-20	Surfactant (substances that have the property of reducing the surface tension of a liquid)
7.	PEG-40	Surfactant (substances that have the property of reducing the surface tension of a liquid)
8.	Chlorhexidine Digluconate	Preservative. Disinfectant with antiseptic action
9.	Anethole	Flavouring
10.	Aroma	Flavouring
11.	Saccharin	Sweetener
12.	Sodium Fluoride	Sodium Fluoride Releasing

Gauze size 6,5x9,5 cm
External envelope size 14x19 cm