

INSTRUCTIONS FOR USE

Softalind® 999

Virucidal Hand Disinfectant

Composition: Active substances: 100 ml solution contain 45 g Ethanol (100%) and 18 g Propan-1-ol. Excipients: Aqua, PEG-90, MEK, Octyldodecanol, Glycerin, pH-regulant E 338 (Phosphoric Acid).
UFI: S9CV-M72V-S00K-K5NP

Product type and efficacy

Softalind® 999 is a new generation of fast action alcohol based hand rubs.

Softalind® 999 combines a superior broad spectrum of activity:

- bactericidal, tuberculocidal and fungicidal activity and
- virucidal activity with shorter application times than traditional alcoholic hand rubs.

Softalind® 999 is a hand rub with skin caring additives and an alcohol content of 63% (w/v) ensures good skin compatibility.

The flashpoint of Softalind® 999 is comparable to traditional alcoholic hand rubs which are used for routine hand disinfection.

Fields of application

Softalind® 999 is the number one hand rub in case of outbreaks and epidemics caused by viruses and in high risk areas.

Hygienic Hand Disinfection

EN1500 - active within 15 seconds

Surgical Hand Disinfection

EN12791 - active within 60 seconds

In-vitro testing

Bactericidal Activity

EN12054 - active within 15 seconds (> 5 log₁₀ reduction)

Tuberculocidal Activity

- active within 15 seconds (> 4 log₁₀ reduction)

Fungicidal Activity (Candida albicans)

EN1275 - active within 15 seconds (> 4 log₁₀ reduction)

Virucidal Activity

Softalind® 999 inactivates enveloped and non-enveloped viruses within 15 s to 30 s (> 4 log₁₀ reduction).

The individual inactivation times are:

Viruses (surrogate resp. model virus) Contact Time

HBV, HCV, HIV (Vaccinia, BVDV)	15 s
Avian Flu / influenza (influenza-A H7N1)	15 s
SARS / corona (BCoV)	15 s
Noro (FCV)	15 s (suspension test) 30 s (fingertips)

rota 15 s

papova 15 s

adeno 30 s

polio 30 s

*All independent laboratory tests are available on request.

Contraindications

Do not use in case of allergy to ethanol or propan-1-ol or any of the other ingredients of Softalind® 999 listed above.

Method of application

Softalind® 999 is applied undiluted to the hands.

Throughout the period of application the skin must remain wetted with the undiluted preparation.

Hygienic hand rub according to EN 1500:

Apply at least 3 ml undiluted Softalind® 999 onto dry hands and rub into the skin. Proceed until the hands are dry. All parts of the hand including the skin areas between the fingers must remain wetted for at least 15 s.

In case of strong, visible contamination of the hands or after contact with Mycobacteria, perform consecutively two hygienic hand rubs.

Inactivation of viruses:

Rub at least 3 ml undiluted Softalind® 999 onto dry hands.

The skin must remain completely wetted with Softalind® 999 for at least 30 s, then allow to dry.

Surgical hand rub according to EN 12791:

Rub several portions of 2 to 3 ml undiluted Softalind® 999 onto dry hands and forearms. The skin must remain completely wetted with Softalind® 999 over a period of at least 60 s, then allow to dry.

Warning statements and precautions for use

– Irritant to the eyes, to injured skin and to mucous membranes! In case of accidental eye contact, the open eye and the inner side of the eyelid has to be rinsed with plenty of water immediately for several minutes. If irritation continues please seek immediate medical advice.

– Flammable! The flash point of the solution is 21°C. At and above that temperature, Softalind® 999 may easily be ignited by sparks, burning cigarettes, open flames and other sources of ignition.

– Do not swallow! If somebody swallows Softalind® 999 inadvertently, he may suffer from acute alcohol poisoning. Immediate emergency medical care is needed. Initiate vomiting under medical advice only.

– Hazard & Precautionary Statements are displayed on the label.

– Pregnancy and Breast-feeding: Softalind® 999 can be used in the recommended way for hand disinfection during pregnancy and lactation.

Undesirable or unintended side-effects

– Alcohol solutions may excitate the skin, especially in seasons of low air humidity (e.g. in winter). Local skin irritation symptoms may result from this (e.g. itching, redness, especially after frequent application).

The application of skin caring hand creams after work is recommended in such cases.

– Allergy to Softalind® 999 occurs very rarely.

In such cases the product must not be used.

– If an allergy is suspected you must go to Occupational Health or Dermatology. A product epicutaneous patch testing kit can be requested directly from B. Braun Medical to test the suspected allergy.

Storage and shelf life

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the label. After the first opening of the container, Softalind® 999 will maintain its quality for 12 months, but not beyond the expiry date.

Pack sizes

Softalind® 999 is available in plastic bottles of 500 ml.

Environmental impact

Ecological injuries are not known or expected under normal use.

Waste management

– Softalind® 999 is classified as hazardous waste (flammability).

It can be deposited in compliance with local official regulations or it can be incinerated in suitable incineration plants. Waste disposal code 070604.

– Contaminated packaging is to be treated in the same way as the product. If there are no official regulations, non-contaminated and completely empty packaging can be treated in the same way as household refuse or recycled.

Recommended cleansing agent: Water

Legal Classification

Softalind® 999 is a biocidal product of Main Group 1:

Disinfectants and general biocidal products, Product-type 1 (Human hygiene biocidal products).

This leaflet was prepared in September 2008.

For professional use.

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Distributor:
B. Braun Medical Ltd.
Thorncliffe Park,
Sheffield, S35 2PW, UK

Manufacturer:
B. Braun Melsungen AG
Carl-Braun-Str. 1,
34212 Melsungen, Germany