

Spitacid Alcohol Hand Rub

Advantages

- **Offers fast acting broad spectrum activity including H1N1**

Proven efficacy against gram positive and gram negative bacteria including MRSA and fungi; and also enveloped viruses. Spitacid is fast acting with proven efficacy against EN 1500 in 30 seconds and removes >99.9% of transient organisms.

- **Comfortable and easy to use**

The emollient gel base maintains and enhances skin comfort throughout the working day. Spitacid Alcohol Hand Rub evaporates quickly and leaves no residue.

- **Flexible and cost effective**

Spitacid Alcohol Hand Rub is supplied in a 500 ml bottle with a flip top. It is suitable for use with the Dermados Maximum 2 dispenser which allows the correct measure of gel to be dispensed and cross contamination is more likely to be avoided. Alternatively, a pump dispenser can be used.



Description

Spitacid Alcohol Hand Rub is designed for the rapid disinfection of physically clean hands. The emollient gel base maintains and enhances skin comfort throughout the working day. The product has been independently dermatologically tested.

The product contains a blend of 70% alcohol with emollients for effective hand sanitising. It evaporates quickly from the skin leaving no residue.

This hand gel offers broad spectrum antimicrobial activity and proven efficacy against gram positive and gram negative bacteria. Spitacid also has proven efficacy against enveloped viruses shown by DVV test work against Bovine Virusdiarrhoea Virus (BVDV) and Vacciniavirus. H1N1 belongs to this group of enveloped viruses. So products with confirmed efficacy against BVDV and vacciniavirus can definitely be assumed effective against Swine Influenza.

It is supplied in a 500 ml flip top bottle. Pump dispensers can be bought separately to add to the bottles if required.

Use biocides safely. Always read the label and product information before use.

Technical Specification

Product composition	Spitacid consists of a v/v formulation of 46 % denatured ethanol and 27 % 2-Propanol in an emollient gel base
Colour	Colourless
Odour	Alcohol
Clarity	Clear
Density (20°C)	0.862 – 0.868 g/cm ³
Refractive index (20°C)	1.368 – 1.374
pH	5.0 – 7.5

Efficacy

Efficacy testing of hand hygiene products supplied by Shield Medicare – a division of Ecolab – is performed to the following standards.

A. EN 12054:2001

Chemical Disinfectants and Antiseptics – Quantitative suspension test for the evaluation of bactericidal activity of products for hygienic and surgical handrub and handwash used in human medicine. Test method and requirements.

B. EN 1500:1998

Chemical Disinfectants and Antiseptics – Hygienic handrub. Test method and requirements.

Standard Tests

Test: prEN 12054

prEN 12054 is a suspension test for establishing whether a hand rub used for post contamination treatment of hands does have bactericidal activity. It is designed to test products that are intended to be used without water.

prEN 12054 employs the following standard organisms.

Organism	Strain
<i>Pseudomonas aeruginosa</i>	ATCC 15442
<i>Escherichia coli</i>	NTCT 10538
<i>Staphylococcus aureus</i>	ATCC 6538
<i>Enterococcus hirae</i>	ATCC 10541

Test Method

1. A standard test suspension of bacteria is prepared. 1 ml of test organism suspension is added and mixed with 9 ml of the hand rub solution. This is left for a contact time of 60 s \pm 5 s. The mixture is maintained at 20°C \pm 1°C.
2. At the contact time a 1 ml aliquot is taken; the bactericidal and/or the bacteristatic action in this portion is immediately neutralised or suppressed by a validated method.
3. The number of surviving bacteria in each sample is determined and the reduction in viable counts is calculated.
4. The mixture was also tested under EN 12054:2001 at 15 s and 30 s contact time.

Results

Table 1: prEN 12054:2001 – 60 s contact time

Organism	Pass Criteria	Conditions	Test Results Log Reduction	Pass/Fail	Validation	Method
<i>P.aeruginosa</i>	Log 5 Reduction	Dirty	> 5.0	PASS	PASS	Dilution Neutralisation
<i>E.coli</i>	Log 5 Reduction	Dirty	> 5.0	PASS	PASS	Dilution Neutralisation
<i>E.hirae</i>	Log 5 Reduction	Dirty	> 5.0	PASS	PASS	Dilution Neutralisation
<i>S.aureus</i>	Log 5 Reduction	Dirty	> 5.0	PASS	PASS	Dilution Neutralisation

Table 2: prEN 12054:1995 – 30 s contact time

Organism	Pass Criteria	Test Results Log Reduction	Pass/Fail	Validation	Method
<i>P.aeruginosa</i>	Log 5 Reduction	> 5.0	PASS	PASS	Dilution Neutralisation
<i>E.coli</i>	Log 5 Reduction	> 5.0	PASS	PASS	Dilution Neutralisation
<i>E.hirae</i>	Log 5 Reduction	> 5.0	PASS	PASS	Dilution Neutralisation
<i>S.aureus</i>	Log 5 Reduction	> 5.0	PASS	PASS	Dilution Neutralisation

Table 3: prEN 12054:1995 – 15 s contact time

Organism	Pass Criteria	Test Results Log Reduction	Pass/Fail	Validation	Method
<i>P.aeruginosa</i>	Log 5 Reduction	> 5.0	PASS	PASS	Dilution Neutralisation
<i>E.coli</i>	Log 5 Reduction	> 5.0	PASS	PASS	Dilution Neutralisation
<i>E.hirae</i>	Log 5 Reduction	> 5.0	PASS	PASS	Dilution Neutralisation
<i>S.aureus</i>	Log 5 Reduction	> 5.0	PASS	PASS	Dilution Neutralisation

Test: EN 1500:1997

EN 1500:1997 employs the following standard organisms.

Organism	Strain
<i>Escherichia coli</i>	ATCC 11229

Test Method

1. Application of test organism to the hands and recovery to obtain a base count.
2. Application of test organism which is dried for 1 min
3. 6 ml of the control and 3 ml product sample is applied to volunteers' hands according to standard hand rub disinfection procedure, performed for both a reference method and the test hand rub.
4. At 30 s contact time an aliquot is taken; the bactericidal and/or the bacteristatic action in this portion is immediately neutralised or suppressed by a validated method.
5. The number of surviving bacteria in each sample is determined and the reduction in viable counts is calculated.

Results

Table 4: EN 1500:1997

	Reference hand rub			Spitacid hand gel		
	Mean Log x	Mean Log y	Log Reduction	Mean Log x	Mean Log y	Log Reduction
Mean	6.06	1.94	4.13	6.34	2.30	4.05
SD	0.40	0.57	0.47	0.37	0.53	0.47

$N = 15$

Mean Log x = log pre-value, average of left and right hand

Mean Log y = log post-value, average of left and right hand

The Pass Criteria is that at least 75 % of the samples achieve a > Log 3 reduction. In this test, 100 % achieved a > Log 3 reduction.

There is no significant difference in the log reduction between the reference hand rub and Spitacid results.

Therefore Spitacid has passed the criteria for EN 1500.

Further Evidence of Efficacy

In order to prove efficacy against yeast and viruses the EN 1275 and DVV methods were employed.

Test: EN 1275:1997

Chemical Disinfectants and Antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas.

EN 1275:1997 employs the following standard organisms.

Organism	Strain
<i>Candida albicans</i>	CIP 4872
<i>Aspergillus niger</i>	CIP1431 - 83

Test Method

1. A test suspension of yeast cells or mould spores is added to a prepared sample of the product under test diluted in hard water.
2. The mixture is maintained at 20°C ±1°C for 15 mins ±10 s (required test conditions).
3. After this contact time an aliquot is taken: the fungicidal action of this portion is immediately neutralised or suppressed by a validated method. The method of choice is dilution neutralisation. If a suitable neutraliser cannot be found, membrane filtration is used.
4. The number of surviving yeast or mould cells in each sample is determined and the reduction in viable counts is calculated.

Results

Table 5: EN 1275:1997

Organism	Pass Criteria	Contact time	Test Results Log Reduction	Pass/Fail	Validation	Method
<i>C.albicans</i>	Log 4 Reduction	5 mins	> 4.0	PASS	PASS	Dilution Neutralisation
<i>A.niger</i>	Log 4 Reduction	15 mins	> 4.0	PASS	PASS	Dilution Neutralisation

Test: EN 1040:1997

Chemical Disinfectants and Antiseptics - Basic bactericidal activity, test method and requirements

EN 1040:1997 employs the following standard organisms.

Organism	Strain
<i>Pseudomonas aeruginosa</i>	CIP103467
<i>Staphylococcus aureus</i>	ATCC 6538

Test Method

1. A test suspension of bacterial cells in a solution of interfering substances is added to a prepared sample of the product under test diluted in hard water.
2. The mixture is maintained at 20°C ±1°C for 15 mins ±10 s (required test conditions).

3. After this contact time an aliquot is taken: the bactericidal action of this portion is immediately neutralised or suppressed by a validated method. The method of choice is dilution neutralisation. If a suitable neutraliser cannot be found, membrane filtration is used.
4. The number of surviving bactericidal cells in each sample is determined and the reduction in viable counts is calculated.

Results

Table 6: EN 1040:1997

Organism	Pass Criteria	Contact time	Test Results Log Reduction	Pass/Fail	Validation	Method
<i>P.aeruginosa</i>	Log 4 Reduction	1 min	> 5.0	PASS	PASS	Dilution Neutralisation
<i>S.aureus</i>	Log 4 Reduction	1 min	> 5.0	PASS	PASS	Dilution Neutralisation

Test: EN 12791

Chemical Disinfectants and Antiseptics – Surgical hand disinfection – Test method and requirements.

Test Method

1. 20 candidates washed their hands with non-antimicrobial soap for 2 mins and then dried them with 1 paper towel per candidate.
2. For determination of the Skin Bacteria fingertips 1 - 5 were inoculated in TSB and the initial colonies are recorded after incubation at $36^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 48 hours.
3. Half (10) of the candidates rubbed their hands with 4 - 6 x 3ml of 60% n-propanol for 5 minutes so that hands remained wet. These are the control for comparison against.
4. The other half (10) of the candidates rubbed their hands with 2 x 5 ml of the test product for 3 mins.
5. The hand was then placed under warm running tap water for 15 secs and an "immediate post value" is recorded from 1 hand of the candidate by inoculation in TSB and the initial colonies are recorded after incubation at $36^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 48 hours.
6. The other hand of the candidate is placed in sterile surgical glove for 3hrs. The sustained post value is measured by inoculation of TSB with the finger tips.
7. 7 days later the experiment was repeated with a reversal of the candidate groups.
8. The statistical difference between the control population and test population is measured to ensure the product provides sufficient efficacy with sustained efficacy, meaning the product can be classified as suitable for surgical hand disinfection.

Results

Table 7: EN 12791 – Reference values

	Immediate effect			3 hour post application effect		
	Pre-values	Post value	Log reduction	Pre-values	Post value	Log reduction
Average CFU	4.53	2.87	1.66	4.48	3.29	4.53
Standard Deviation	0.50	0.62	0.61	0.47	0.67	0.50

Table 8: EN 12791 – Spitacid values

	Immediate effect			3 hour post application effect		
	Pre-values	Post value	Log reduction	Pre-values	Post value	Log reduction
Average CFU	4.45	2.85	1.61	4.52	3.11	1.42
Standard Deviation	0.41	0.59	0.45	0.38	0.49	0.43

There is no statistical difference in the immediate efficacy of Spitacid compared against the reference hand disinfection. There is an improvement in the 3 hour post storage efficacy of Spitacid compared against the reference hand disinfection. Spitacid has been classified as suitable for surgical hand disinfection passing the criteria for EN 12791.

Investigation 1

Test house –University Hospital of Essen, Germany

Suspension test to establish the efficacy of Spitacid against Hepatitis B after 30 s and 5 mins contact time at room temperature (20°C ±1°C). MADT methodology was used.

The following organisms were employed:

Organism
Hepatitis B

Results

Organism	Pass Criteria	Results (Log Reduction)		Pass/Fail
		Clean	Dirty	
Hepatitis B after 30 s	Log 4 reduction	> 4.0	> 4.0	PASS
Hepatitis B after 5 mins	Log 4 reduction	> 4.0	> 4.0	PASS

Investigation 2

Test house – Institut Pasteur, Paris

The purpose of this study was to determine the efficiency of Spitacid to inactivate both the reverse transcriptase and the infectivity for CD₄⁺ cells (CEM-CI 13) of the AIDS virus Human Immunodeficiency virus (HIV). The tests were conducted after 1, 2.5 and 5 mins contact time at room temperature (20°C ±1°C).

Method

Aliquots of Human Immunodeficiency Virus HIV were treated with Spitacid for the contact time. Positive and negative control samples were set up to ensure that both the cell and virus would survive during the time course of the experiment. Samples were diluted after the contact time and the virus was incubated with cells to allow measurement of the reverse transcriptase activity.

Results

Organism	Contact time	Results (reduction of RT activity)
HIV	1 min	> 99%
HIV	2.5 min	> 99%
HIV	5 min	> 99%

Investigation 3

Test house – National Institute of Hygiene, Bremen

Suspension test to establish the efficacy of Spitacid against Rotavirus, in order to be representative of efficacy against strains of Poliovirus and Adenovirus. The tests were conducted after 30 s, 1 min, 3 min and 5 min contact time at room temperature (20°C ±1°C).

Rotavirus is worldwide one of the main causative agents of food-borne Enteritis infections, especially with children, and the hands are the most usual method of cross infection.

DVV Test Method *(according to German Association for the Control of Virus Diseases)*

1. Preparation of the viral suspension.
2. Preparation of disinfectant without protein and with 10 % fetal calf serum.
3. The virus is then exposed to the disinfectant preparation for the contact time.
4. 10 fold serial dilutions of the contact samples are prepared.
5. The dilutions are inoculated into cell culture and incubated.
6. CPE/cell death is recorded and the log reduction is calculated.

Results

Organism	Pass Criteria	Contact Time	Results (Log Reduction)	Pass/Fail
			Clean Conditions	
Bovine Rotavirus	Log 4 reduction	30 s	> 4.0	PASS
Bovine Rotavirus	Log 4 reduction	1 min	> 5.0	PASS
Bovine Rotavirus	Log 4 reduction	3 min	> 5.0	PASS
Bovine Rotavirus	Log 4 reduction	5 min	> 5.0	PASS

Investigation 4

Suspension test to establish the efficacy of Spitacid against enveloped viruses after 30 s and 60 s contact time at room temperature (20°C ±1°C).

The following organisms were employed:

Organism	Strain
Vacciniavirus	Elstree
Bovine virus diarrhoea virus (BVDV)	NADL

Results

Organism	Pass Criteria	Results (Log Reduction)		Pass/Fail
		Clean	Dirty	
Vacciniavirus after 30 s	Log 4 reduction	> 4.0	> 4.0	PASS
Vacciniavirus after 60 s	Log 4 reduction	> 4.0	> 4.0	PASS
BVDV after 30 s	Log 4 reduction	> 4.0	> 4.0	PASS
BVDV after 60 s	Log 4 reduction	> 4.0	> 4.0	PASS

Instructions for use

Wash hands correctly with soap and water and dry them thoroughly. Alcohol gels must only be used on physically clean hands.

Administer sufficient gel to cover hands. A single depression of the pump should be adequate for most users.

Rub thoroughly into the hands ensuring complete coverage – see the suggested technique below. Continue rubbing until the gel has evaporated and the hands are dry.

Guidelines for Hand Disinfection

developed by the Hand Hygiene Liaison Group



1 Apply alcohol gel to the palm of one hand.



2 Press fingertips of the other hand to the palm.



3 Tip the remaining alcohol from one palm to the other.



4 Press fingertips of the other hand to the palm.



5 Quickly spread alcohol onto all surfaces of both hands.



6 Continue spreading the alcohol until it dries.

Guidelines for hand washing

Ayliffe Technique

1. Palm to palm

2. Right palm over left dorsum and left palm over right dorsum

3. Palm to palm fingers interlaced

4. Backs of fingers to opposing palms with fingers interlocked

5. Rotational rubbing of right thumb clasped in left palm and vice versa

6. Rotational rubbing, backwards and forwards with clapsed fingers of right hand in left palm and vice versa

Validation

Manufactured by an EN ISO 9001:2000 accredited company.

Spitacid Alcohol Hand Rub is currently tested to EN 1040, EN 1275, prEN 12054, EN 1500 and prEN 12791.

Spitacid Alcohol Hand Rub has a 3 year shelf life.

Product Codes

Code	Description	Size	Unit of Sale
3044100	Spitacid Alcohol Hand Rub	500 ml	24 bottles x 500 ml
810095080352	Dermados Maximum 2 dispenser		Each
7-1004110	Pump dispenser 1 ml		50 pcs/pack

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