



**EXPERTS IN OCCUPATIONAL HAND HYGIENE**



# Cutan Foam Hand Sanitiser Summary of Microbiological and Skin Testing

*Cutan*<sup>®</sup>

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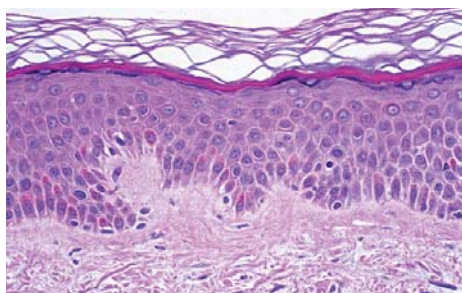


# Section 1:

## Product Overview

### Product Description

A unique alcohol-based foaming hand sanitiser for use by Healthcare workers. This product kills transient and some resident micro-organisms present on the skin and helps prevent the spread of infections.



Normal Epidermis and Dermis

### Product Usage

For use on physically clean hands without the need for rinsing with water. The following are examples of when hands should be sanitised in a healthcare environment. It is far from an exhaustive list, but it should prove a useful guide.

- When entering and leaving a patient care environment e.g. a ward, a ward bay or treatment room
- Before and after dressing wounds, handling catheters and IV lines etc.
- Before and after caring for susceptible patients, particularly those that are immunocompromised
- Before and after administering medication
- Before and after touching notes, telephones and computer key boards
- Prior to all surgical procedures, after hand washing
- After handling dirty laundry or waste
- Before and after donning sterile gloves
- Before preparing or handling food

### Key Product Features

- **Unique foam format** - spreads quickly and easily across the hands, preventing spills and splashes and ensuring all product is used with no wastage
- **Rapid sanitising action** - works in seconds to kill transient micro-organisms
- **Effective against a broad spectrum of micro-organisms** - kills most common bacteria, yeasts, moulds and viruses
- **Gel-free formula** - does not contain any gelling agents which are known to clog dispensers and pumps and leave a sticky after-feel on the skin
- **Contains moisturiser** - regular use actually helps improve skin condition
- **Improves compliance** - study shows preference for Cutan Foam Hand Sanitiser compared to traditional alcohol gels, leading to increased compliance





Product	Pack Size	Stock Code
<i>Cutan Foam Hand Sanitiser</i>	25 x 50ml	CFS50ML
<i>Dispenser</i>	12 X 400ml	CFS400P
<i>Multi-fix Bracket</i>	6 x 1 litre Cartridge	CFS39H
	For 1 litre Cartridge	CSS39A
	400ml Bracket	BRK400ML



A clip is available for the Cutan Foam Hand Sanitiser 50ml bottle, which allows the pack to be conveniently clipped onto clothing, providing portability to staff who are constantly on the move.



Multi-fix brackets can be stuck or screwed to surfaces, hooked over furniture or clamped to rails (with diameters between 5mm - 25mm) running vertically or horizontally.

## Pack Sizes and Codes

Cutan Foam Hand Sanitiser is available in three pack sizes to suit users needs in healthcare environments:



- 50ml staff carried personal issue pump pack
- Stock Code: CFS50ML



- 400ml pump-top bed-end or near patient pack
- Stock Code: CFS400P



- 400ml Multi-fix bracket for bed-ends, trolleys, cabinets etc
- Stock Code: BRK400ML



- 1 litre ultra-sonically sealed cartridge
- Stock Code: CFS39H



- Wall mounted dispensing system for 1 litre cartridge
- Stock Code: CSS39A

All packs are clearly coloured in red for ease of identification and are fully supported with the unique range of Cutan training and educational support materials.

# Section 2: Summary of Tests

## Summary of Tests Conducted

Test Category	Test Description
<i>Microbiological</i>	<b>Bactericidal</b> <ul style="list-style-type: none"><li>• European Standard Test EN1500</li><li>• European Standard Test EN1276</li><li>• Rapid Germicidal (Kill Time) Activity</li></ul> <b>Fungicidal</b> <ul style="list-style-type: none"><li>• European Standard Test EN1275</li></ul> <b>Virucidal</b> <ul style="list-style-type: none"><li>• ASTM Method E 1052-96</li></ul>
<i>Skin Tests</i>	Trans Epidermal Water Loss (TEWL) Test 48 Hour Patch Test Skin Hydration Test Toxicological Assessment Taint Test

## Encourages Compliance

Cutan Foam Hand Sanitiser has been tested for skin compatibility in tests to mirror actual use and the effects of prolonged contact. The results of these tests demonstrated that regular use of the product did not harm the skin. As a consequence, users can be assured that regular use will not lead to deterioration in the condition of their hands, meaning that high rates of compliance can be achieved.

## Improved Hygiene

Cutan Foam Hand Sanitiser is free from thickening agents commonly found in alcohol gels. As a result there is no possibility of dispensing nozzles and pumps becoming blocked by dried gel residues, which can result in the alcohol gel spraying unpredictably from dispensers and leaving unsightly marks on floors and walls, not to mention the complete elimination of a slip hazard as a result of gel spillage on floors.



# Section 3:

## Microbiological Test Results

### Test Name: BS EN1500:1997

An in vivo test to determine the ability of a hand sanitiser to reduce transient microbial contaminants when used in a hygienic hand rub procedure.

#### Objective:

The objective of this study was to assess the antimicrobial effectiveness of a foam hand sanitiser, (Cutan Foam Hand Sanitiser) compared to a standard reference control (60% v/v propan-2-ol), in producing an immediate reduction in transient bacteria on the hands. The comparison with a known standard reference provides assurance of a reliable estimation of the effectiveness of the test product.

#### Methodology:

A total of 15 subjects took part in the study to evaluate the test product, (Cutan Foam Hand Sanitiser) and control, (60% v/v propan-2-ol). The hands of the subjects all had healthy skin, free from cuts and abrasions and with short finger nails. The design of this study was as specified under the requirements of EN1500.

The release of test organisms (Escherichia coli NCTC 10538) from the fingertips of artificially contaminated hands is assessed before and after the application of the test product, (Cutan Foam Hand Sanitiser). The ratio of these two values is a measure of the antimicrobial activity of the test product. This value is then compared to the value obtained for a reference product, (60% v/v propan-2-ol) tested on the same subjects on the same day and under comparable environmental conditions.

The mean reduction of the release of test organisms achieved by the test product shall not be significantly smaller than that obtained by the reference product.

#### Results:

The test product, Cutan Foam Hand Sanitiser, showed a mean log reduction that was not significantly smaller than the control, (60% v/v propan-2-ol).

#### Conclusion:

The test product, Cutan Foam Hand Sanitiser, was found to meet the requirements of EN1500 with a test time of 30 seconds.

### Test Name: BS EN1276:1997

This is an in vitro test, performed under "clean" and "dirty" conditions.

#### Objective:

The objective of this study was to substantiate the bactericidal effectiveness of Cutan Foam Hand Sanitiser.

#### Methodology:

The "clean" condition incorporates 0.03% bovine albumin and the "dirty" condition 0.3% bovine albumin. This substance simulates the presence of dirt on the hands.

The test product is brought into contact with a known number of the test bacteria for a specified time, one of which must be 5 minutes. The product is then neutralised and the number of surviving bacteria are counted. The log reduction is then calculated. This must be at least 5 for all organisms tested in order for the product to pass the test.

#### Results:

Organism	Conditions	Time (min)	Log Reduction
<i>Escherichia coli</i> <i>ATCC 10536</i>	Clean and Dirty	1 and 5	>5
<i>Staphylococcus aureus</i> <i>ATCC 6538</i>	Clean and Dirty	1 and 5	>5
<i>Pseudomonas aeruginosa</i> <i>ATCC 15542</i>	Clean and Dirty	1 and 5	>5
<i>Enterococcus hirae</i> <i>ATCC 10541</i>	Clean and Dirty	1 and 5	>5
<i>Salmonella typhimurium</i> <i>ATCC 13311</i>	Clean and Dirty	1 and 5	>5
<i>Listeria monocytogenes</i> <i>NCTC 10357</i>	Clean and Dirty	1 and 5	>5

#### Conclusion:

Cutan Foam Hand Sanitiser passed the requirements of EN1276 and also satisfied this test at a time of 1 minute.

## Test Name: Assessment of Rapid Germicidal (Time Kill) Activity

This is an in vitro study to determine the antimicrobial properties of Cutan Foam Hand Sanitiser.

### Objective:

The objective of this study was to measure the ability of Cutan Foam Hand Sanitiser to reduce a known concentration of micro-organisms over a specified period of time.

### Methodology:

A portion of Cutan Foam Hand Sanitiser was brought into contact with a known concentration of test organisms for a defined period of time. The product was then neutralised and a sample removed to determine the concentration of survivors. The percent reduction and the log reduction from the original population was calculated.

In this study, one type of yeast and sixteen types of bacteria were tested at a 15 second exposure time.

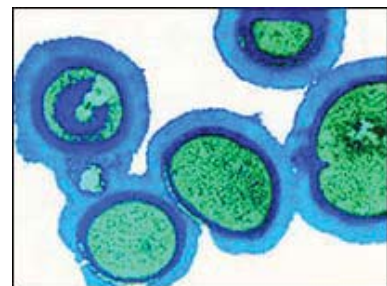
### Results:

Organism	ATCC No	Exposure Time (Seconds)	%Reduction	Log Reduction
<b>Yeast</b>				
<i>Candida albicans</i>	10231	15	99.999	5
<b>Bacteria</b>				
<i>Enterococcus faecium (VRE)</i>	51559	15	99.999	5
<i>Escherichia coli</i>	11229	15	99.999	5
<i>Escherichia coli 0157:H7</i>	35150	15	99.999	5
<i>Escherichia coli</i>	25922	15	99.999	5
<i>Haemophilus influenzae</i>	19418	15	99.999	5
<i>Klebsiella pneumoniae</i>	11296	15	99.999	5
<i>Proteus mirabilis</i>	7002	15	99.999	5
<i>Pseudomonas aeruginosa</i>				
	9027	15	99.999	5
<i>Salmonella choleraesuis</i>	10708	15	99.999	5
<i>Staphylococcus aureus</i>	6538	15	99.999	5
<i>Staphylococcus aureus (MRSA)</i>				
	33591	15	99.999	5
<i>Staphylococcus aureus (MRSA)</i>				
	33592	15	99.999	5
<i>Staphylococcus epidermidis</i>				
	12228	15	99.999	5
<i>Staphylococcus epidermidis (MRSE)</i>				
	51625	15	99.999	5
<i>Staphylococcus haemolyticus</i>				
	29970	15	99.999	5
<i>Streptococcus pyogenes</i>				
	19615	15	99.999	5

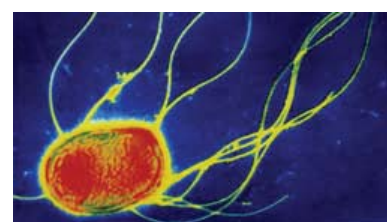
### Conclusion:

After 15 seconds of exposure to Cutan Foam Hand Sanitiser a 5 log reduction in the numbers of test organisms was shown for all organisms tested. This is equivalent to the elimination of 99.999% of the original population.

Cutan Foam Hand Sanitiser is a broad spectrum and fast acting antimicrobial agent.



Staphylococcus aureus (MRSA)



Salmonella choleraesuis



Escherichia coli (E.coli)

### Test Name: BS EN1275:1997

This is an in vitro test using a yeast and a mould as the test organisms.

#### Objective:

The objective of this study was to substantiate the fungicidal effectiveness of Cutan Foam Hand Sanitiser.

#### Methodology:

The test product is brought into contact with a known number of test fungi for a specified time, one of which must be 5, 15, 30 or 60 minutes.

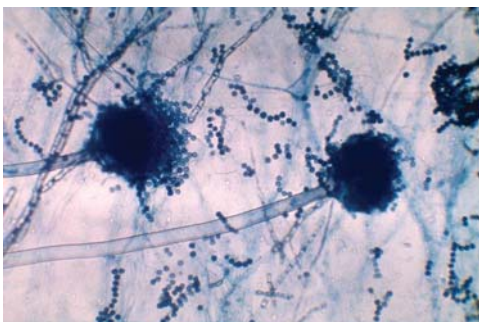
The product is then neutralised and the number of surviving fungi are counted. The log reduction is then calculated. This must be at least 4 for both organisms in order for the product to pass the test.

#### Results:

Organism	Time (min)	Log Reduction
<i>Candida albicans</i> <i>NCPF/NCTC 3179</i>	1 and 5	>4
<i>Aspergillus niger</i> <i>NCPF/NCTC 2275</i>	1 and 5	>4

#### Conclusion:

Cutan Foam Hand Sanitiser satisfied the requirements of EN1275 at 5 minutes and also passed this test at a time of 1 minute.



*Aspergillus niger*

### Test Name: ASTM Method E 1052-96

An in vitro test used to evaluate the effectiveness of antimicrobial solutions against specific viruses.

#### Objective:

The objective of this study was to measure the ability of Cutan Foam Hand Sanitiser to reduce a known virus population after a specified time. For the purposes of this study, the viruses concerned were Influenza A, (ATCC VR-1469) and Coronavirus Murine Hepatitis, (ATCC VR-764).

#### Methodology:

An aliquot of the test material, Cutan Foam Hand Sanitiser, was brought into contact with a known population of the test virus for a specified period of time (15 seconds).

The test product was then neutralised at the end of the 15 second test period and a sample taken to measure the numbers of survivors. A reduction in the virus concentration over a parallel control within the specified exposure time is calculated, and reported as the percent reduction and the log reduction from the original population.

#### Results:

Cutan Foam Hand Sanitiser showed a 3.8 log reduction, equivalent to greater than a 99.9% reduction in the original test virus concentration for Influenza A Virus, at an exposure time of 15 seconds.

For Coronavirus Murine Hepatitis Virus the results were a 4.0 log reduction, equivalent to a 99.99% reduction in the original test virus concentration, also at an exposure time of 15 seconds.

#### Conclusion:

Cutan Foam Hand Sanitiser exhibits rapid antiviral activity



# Section 4:

## Skin Test Results

### Test Name: Trans Epidermal Water Loss (TEWL) Test

Measures the rate at which water is being lost from the skin, which in turn indicates if the barrier function of the skin has been impaired.

#### Objective:

To examine the effect of frequent usage of Cutan Foam Hand Sanitiser on the treated and untreated hands of volunteers using Trans Epidermal Water Loss measurements.

#### Methodology:

The Trans Epidermal Water Loss was measured by an instrument called a Tewameter. The probe on this instrument measures the amount of water that is lost through the outer layer of the skin. Irritated or damaged skin does not hold water very well and as a result water is easily lost and skin can become dry and cracked.

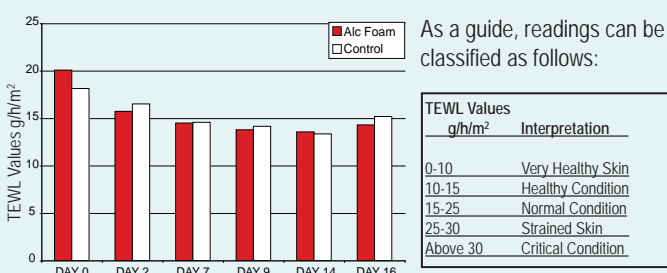
30 subjects applied the product over a period of 16 days. One application of the product was used 10 times a day and rubbed around the hands according to the "how to use" instructions. One hand was gloved during this technique and this served as the control (i.e. no skin sanitiser). A measurement was taken twice a week on the back of the hands, under controlled conditions (the subjects acclimatised for 20 minutes in the testing laboratory).

The measurements are then evaluated statistically.

#### Results:

	DAY 0	DAY 2	DAY 7	DAY 9	DAY 14	DAY 16
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Alc. Foam	20.08	15.73	14.5	13.79	13.57	14.3
Control	18.14	16.51	14.57	14.16	13.35	15.19



#### Conclusion:

From these results we can conclude that for the individuals involved in the study, the rate of water loss from the treated hand was slightly less than for the untreated hand. This in turn indicates that the moisture retained in the skin was higher for the treated hand compared to the untreated hand. This would infer that the regular use of Cutan Foam Hand Sanitiser improves skin condition and certainly has no detrimental effect upon it.

### Test Name: 48 Hour Patch Test

An in vivo test involving 25 human volunteers to assess skin irritancy.

#### Objective:

A Patch Test (or Primary Irritation Test) is performed in order to assess whether a product might cause any skin irritation to the user.

#### Methodology:

An occlusive (impenetrable) patch containing the test product is applied to the upper arm of the subject. A total of 25 subjects are used for the test.

After around 23 hours, the patch is removed, the area is wiped clean and 1 hour later the test site is assessed for irritation.

Assuming no skin reaction, a second patch is then applied and worn for a further 23 hours. Again the assessment of the skin is done 1 hour after the removal of the patch.

The skin condition is evaluated by trained assessors and each subject is given an irritation score.

#### Results:

The Mean Irritation Score for Cutan Foam Hand Sanitiser is 0.52 after 48 hours. This puts the product into the "Very Mild" category.

#### Conclusion:

Cutan Foam Hand Sanitiser can claim to be "Dermatologically Tested".

## Test Name: Skin Hydration Test

Measurements made using a Corneometer give rise to values that are directly attributable to the moisture content of the outermost layer of the skin (the stratum corneum). This type of measurement is indicative of skin condition.

### Objective:

To examine the effect of frequent usage of Cutan Foam Hand Sanitiser on the treated and untreated hands of volunteers using corneometer measurements.

### Methodology:

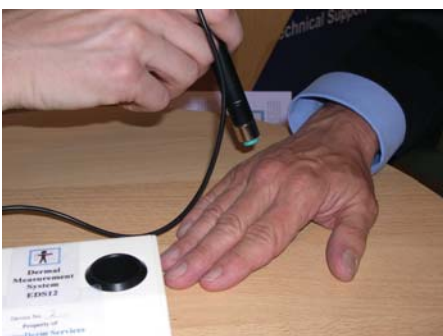
The moisture content of the stratum corneum was measured using an instrument called a corneometer.

The probe on this instrument measures the level of hydration in the outermost layer of the skin (the stratum corneum), i.e. how much water the skin holds. The higher the level of hydration in the skin, the more supple and soft the skin feels.

30 subjects applied the product over a period of 23 days. One application of the product was used 10 times a day and rubbed around the hands according to the "how to use" instructions.

One hand was gloved during this technique and this served as the control (i.e. no skin sanitiser). To evaluate the hydration, 5 measurements from the back of the hand are taken and the average of these is recorded. These measurements were taken twice a week under controlled conditions (the subject acclimatised for 20 minutes in the testing laboratory).

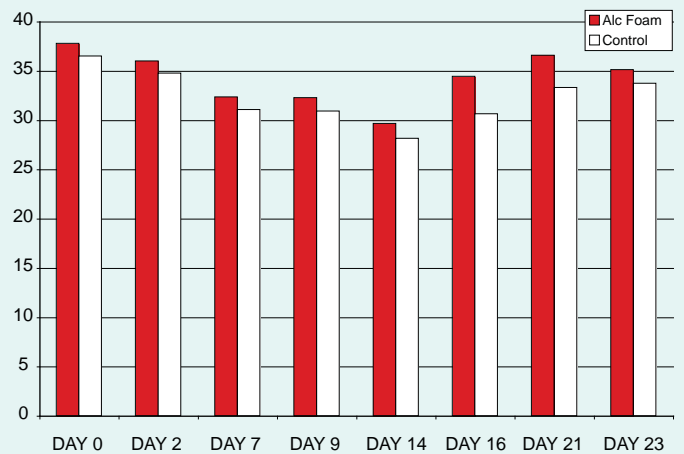
The measurements are then evaluated statistically.



Corneometer in use

### Results:

	DAY 0	DAY 2	DAY 7	DAY 9	DAY 14	DAY 16	DAY 21	DAY 23
Alc. Foam	37.78	36.01	32.36	32.37	29.66	34.45	36.58	35.11
Control	36.51	34.77	31.08	30.91	28.14	30.64	33.31	33.74



Values are valid for healthy skin and normal room conditions (20°C and 40-60% air humidity).

### Conclusion:

The regular use of Cutan Foam Hand Sanitiser increased the moisture content in the outermost layer of the skin in those individuals investigated.

## Test Name: Taint Test

### Objective:

To determine whether the product has the potential to taint food.

### Methodology:

The Triangle Test Method is used. The test product is applied to the test technician's hands as per the manufacturers "how to use" instructions. This action is then repeated (to simulate a worst case scenario). After 5 minutes the test technician performs a simple handling exercise on half of the quantity of chocolate buttons being used for the test.

Prior to preparing the treated chocolate buttons, control chocolate buttons are also prepared, in this case using clean, dry hands to handle the chocolate (i.e. no skin sanitiser applied to the hands).

The treated and control chocolate samples are then evaluated by 30 trained assessors to determine whether any taint can be detected in the treated chocolate samples. The assessors sit in an individual booth which is positively pressurised to minimise the entrance of external odours. Blue coloured lighting is used to mask any colour difference between the samples.

If more than 11 of the assessors can identify the different samples, then the product may have the potential to taint food.

### Results:

Only 7 of the 30 assessors correctly identified the treated sample.

### Conclusion:

Statistically there is no significant difference between the samples. Therefore Cutan Foam Hand Sanitiser does not have the potential to taint food.

## Test Name: Toxicological Assessment

### Objective:

The objective of this type of study is to evaluate a cosmetic product (i.e. any product used on the skin) for any potential adverse reactions.

### Methodology:

The ingredients of the product are assessed by a toxicologist.

The ingredients must be legally permitted as per the relevant Annexes within the EU Directive 76/768/EEC and its amendments.

The toxicologist will assess the type of product and the typical usage levels of it – how much, how often, for how long (is the product rinsed off or left on the skin), what area of the body is, or might be, exposed to the product etc.

### Results:

The report from the toxicologist declared that the product is non-toxic.

### Conclusion:

Cutan Foam Hand Sanitiser gives users the level of safety they can reasonably expect.



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**For further help and advice contact Deb Technical Services Hotline  
Tel: 01773 880367**

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