

PA  
DISPERSION  
TECHNOLOGY



safe  
CLEANSE  
gel

kills viruses,  
bacteria and fungi

[www.safecleanse.com](http://www.safecleanse.com)

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# safe CLEANSE gel

## Activities

SafeCleanse™ uses a patented, innovative and proven anti-viral control technology to kill and control viral organisms, including H5N1. A combination of very low toxicity, broad spectrum efficacy and residual, long lasting effectiveness make for an extremely versatile virocidal with innumerable uses in the food processing, healthcare and general industrial sectors.

## Key Facts

- Kills 90% of tested viruses, bacteria and fungi within 30 seconds
- Kills 99.99% of tested viruses, bacteria and fungi within 5 minutes
- Up to 3 hours long lasting protection
- Non toxic to humans or animals
- Will not damage the skin
- Low PH mimics the skin
- Patented PA Dispersion Technology
- Technology is safe and proven

## Presentation

- 50ml Personal disinfection unit  
– up to 50 treatments
- 150ml Personal disinfection unit  
– up to 150 treatments
- 500ml washing station pump  
– up to 500 treatments
- 1000ml washing station pump  
– up to 1000 treatments

## Independent testing undertaken by:

RetroScreen Virology Ltd, Francis Bancroft Building  
Barts & The London Queen Mary's School of Medicine  
London E1 4NS

Due to its physical architecture SafeCleanse™ is not considered to be a new compound.

SafeCleanse™ is the registered trademark of DermaSalve Sciences plc the AIM listed pharmaceutical company (Epic DRM).

DermaSalve floated on AIM in January 2006 and is developing a complete range of Anti Virocidal and Anti Microbial treatments under its SafeCleanse™ brand name.

## Products include:-

- SafeCleanse™ viral disinfectant
- SafeCleanse™ Wipes anti viral wipes
- SafeCleanse™ Bact anti microbial gel
- SafeCleanse™ Scrub Surgical scrub



# SafeCleanse™ Cleaning Up Avian Flu Infections

SafeCleanse™ is a pleasant easy and safe to use gel which has been proven to be highly effective against Avian Influenza a nibrg-14 (H5N1) by one of the world's leading virus testing laboratories ('RetroScreen Virology').

With the recent news of a possible H5N1 pandemic the need to prevent any opportunities of transmission of the virus between avian species and humans has arisen. A safe anti viral agent would be ideal for use in poultry farms or quarantine units to prevent species to-species transmission of the virus.

In addition, if the virus did cross the species barrier healthcare workers, research scientists and the general public would benefit from a hand wash against the H5N1 virus to prevent indirect transmission of the virus. Indirect transmission commonly occurs by touching the eyes, nose or mouth after contact with surfaces contaminated by the virus.

RetroScreen Virology showed that SafeCleanse™ reduced the level of Avian Influenza ERG-14 "H5N1" by at least 99.99% over 5 minutes and by 90% within 30 seconds. Additionally, Retro Screen reported that SafeCleanse™ did not do any observable damage to vulnerable test cells.

SafeCleanse™ was observed to reduce the virus titre of Avian Influenza A NIBRG-14 (H5N1) by >4.00—log<sub>10</sub> TCID<sub>50</sub>/ml (>99.99%) over the 5 minute, 10 minute and 30 minute incubation time points at a test concentration of 90% (v/v) (Table 2).

SafeCleanse™ was observed to reduce the virus titre of Avian Influenza A NIBRG-14 (H5N1) by 1.00—log<sub>10</sub> TCID<sub>50</sub>/ml (90.00%) over the 30 second incubation time points at a test concentration of 90% (v/v) (Table 2).

There was no observed cytotoxicity on the MDCK cell line at any serial dilution after treatment with Sephadex® filtered SafeCleanse™ lotion 90% (v/v) (Table 1)

SafeCleanse™ has the ability to transform the disinfection of a broad spectrum of viruses.

Serial Dilution (10 <sup>x</sup> )	SafeCleanse™			
0A	-	-	-	-
-1	-	-	-	-
-2	-	-	-	-
-3	-	-	-	-
-4	-	-	-	-
-5	-	-	-	-
-6	-	-	-	-
CellOnly	-	-	-	-

**Table 1: tCPE Observations of the MDCK cell monolayer after treatment with SafeCleanse™**

**Key:** F= Fixed cells, fixation is deemed a toxic effect

T= positive for tCPE      == negative for tCPE

# SafeCleanse™

## The hypoallergenic anti-viral gel of choice

Treatment	Contact time	Virus titre recovered (-log10 TCID50/ml)		Reduction in virus titre	
		Virus control	Test article	(-log10 TCID50/ml)	(%)
SafeCleanse™ gel 90% (v/v)	30 sec	5.50	4.50	1.00	90.00
SafeCleanse™ gel 90% (v/v)	5min	5.50	1.50	4.00 ~	99.99
SafeCleanse™	10min	5.50	1.50	4.00 ~	99.99

SafeCleanse™ is classified as a biocide. SafeCleanse™ products use patented PA Dispersion Technology to produce a highly effective and safe gel with anti viral activity.

In combination the efficacy of each biocide is significantly amplified by the use of PA Dispersion Technology – which makes it pleasant to use, making user compliance with hygiene protocols more likely. The product architecture has thus been crucial to establishing patent protection and product use approvals for SafeCleanse™ as it is not considered to be a new substance or compound.

Whilst SafeCleanse™ is effective at killing viruses it is its ability to combine biocidal levels of alcohol with the ability to use it with great frequency without damage to skin that uniquely sets it far apart from anything else in the market. SafeCleanse products have the following key characteristics:

- Effectiveness: SafeCleanse™ retains biostatic activity after it has dried, providing protection for up to 3 hours after use.
- Broad based killing power: SafeCleanse™ is effective against a very wide range of micro-organisms including hospital superbugs such as MRSA and VRE as well as H5N1 Bird Flu Virus. SafeCleanse products can be used as a cleaner, sanitizer, and deodoriser...
- Low risk of resistance: Due to the structure and action of SafeCleanse™, organisms are eradicated in such a way that they appear not to develop any resistance.
- Frequent use without damage or discomfort to skin: Leaves the hands feeling moisturised after use. Use as frequently as required.
- Very low toxicity: The SafeCleanse™ PA Dispersion Technology ensures the product is safe to use on humans and in contact with foods and plants, and does not leave a toxic residue.
- Easy to use: SafeCleanse™ is simple and safe to apply and no training or special safety precautions are required.
- Environmentally friendly: SafeCleanse™ is fully biodegradable.

# safe CLEANSE gel

## Activities

SafeCleanse™ Gel has been specially formulated with moisturisers for sensitive skin using PA Dispersion Technology to provide effective infection control against a wide range of viruses, bacteria, fungi, yeasts and moulds. It is pH balanced, Perfume free and dermatologically tested and exhibits no cytotoxic effects against skin cells. Kills 99.99% of organisms\* in 30 seconds.

For use as a skin biocide in healthcare, food preparation, animal handling and general hygiene. Tested under with EN1500 and EN1276.

## Directions for use:

Do not use water. Remove cap and press top so that 1 ml of lotion is squirted onto the palm of one hand. Rub front and back of hands together including between fingers until gel is absorbed.

## Safety Instructions:

Flammable, store at room temperature out of direct sunlight and sources of ignition. Avoid contact with eyes. For external use only. Keep out of reach of children.

Disposal – Drain well and dispose of as normal household waste

Active ingredients: Ethanol 60.49% w/w,  
Triclosan 0.1 % w/w

Independent testing undertaken by:

## Microbiological Solutions Ltd

141 a– 143a Bury New Road,  
Whitfield, Manchester, M45 6AA



# SafeCleanse™ the hypoallergenic anti-microbial gel of choice

SafeCleanse™ is a pleasant easy and safe to use gel which has been proven to be highly effective against a wide spectrum of microbial and fungal infections within 30 seconds by leading testing laboratories (\*Microbiological Solutions Ltd). SafeCleanse™ has been tested to the following European and USA Standards: EN1500 (transient bacteria), EN1275 (yeasts and moulds) and EN 1276 (food handling) and FDA 21 CFR 333 470 (a) (iv) 4. (The latter was tested on a slightly different USA formulation).

The patented PA Dispersion Technology includes skin moisturisers that permit repeated frequent usage without skin damage. The gel does not need water and has a cosmetic quality feel. This unique feel and user friendly technology creates higher user compliance and reduced indirect transmission which commonly occurs by touching the eyes, nose or mouth after contact with surfaces contaminated by the virus.

## Dermatological issues

Manufactured from pharmaceutical grade materials  
Not perfumed

No additional preservatives

Very low level of surfactants (0.06%)

Low pH 6.7 will not damage skin acid mantle

PA Dispersion Technology prevents cytotoxic skin cell damage

SafeCleanse™ has been specifically tested for Germicidal Germ

Kill against the following organisms:-Staphylococcus aureus AT

CC 6538 Psuedomonas aeruginosa ATCC 9027 Listeria

monocytogenes ATCC 7644 Salmonella typhimurium ATCC

14028 Enterococcus hirae ATCC 10541 Mycobacterium

smegmatis NCIMB 131 16 Methicillin Resistant Staphylococcus

aureus NCTC 12493 Klebsiella pneumoniae (Wild)

Enterococcus faecalis ATCC 29212

Escherichia coli ATCC 8739

Escherichia coli NCTC 12900

Shigella sonnei (Wild)

Staphylococcus epidermidis ATCC 12228

## Spore Formers:

Candida albicans ATCC 10231

Aspergillus niger NCPF 2275

Bacillus cereus NCTC 7461

The tests were carried out on the SafeCleanse™ product supplied in bulk Batch Number FNI60/3 511

## Antimicrobial and Spore Former Test Results.

### Test Results Summary

The results of the tests show a good log reduction of at least 7 for most bacteria and 4 for the yeast and mould with the exception of the Bacillus cereus which only gave a log reduction of 2

### Suspension Test Results

Sample	Lab Number	Organism	Inoculum Level	Time/Log Reduction		Overall log Reduction
				30s	5min	
SafeCleanse Alcohol Gel	4037/01	S.aureus ATCC 6538	4.5x10 <sup>11</sup>	8	0	8
		P.aeruginosa ATCC 9027	3.1 x10 <sup>8</sup>	8	0	8
		L.monocytogenes ATCC 7644	4.8x10 <sup>8</sup>	8	0	8
		S.typhimurium ATCC 14028	5.4x10 <sup>8</sup>	8	0	8
		Ent hirae ATCC 10541	2.7x10 <sup>8</sup>	8	0	8
		M.smegmatis NCIMB 13116	3.8x10 <sup>8</sup>	8	0	8

### Bacterium Test Results

Sample	Lab Number	Organism	Inoculum Level	Time/Log Reduction 30s	Time/Log Reduction
SafeCleanse Alcohol Gel	4037/01	MRSa NCTC 12493	3.0x10 <sup>8</sup>	7	7
		K. pneumoniae WILD	3.4x10 <sup>8</sup>	8	8
		Ent faecalis ATCC 29212	3.4x10 <sup>8</sup>	8	8
		E.coli ATCC 8739	3.64x10 <sup>11</sup>	7	7
		S.sonnei WILD	2.94x10 <sup>8</sup>	8	8
		S.epidermidis ATCC 12228	1.5x10 <sup>8</sup>	8	8
		E.coli 0157 NCTC 12900	1.3x10 <sup>8</sup>	8	8

### Suspension Test Results

Sample	Lab Number	Organism	Inoculum Level	Time/Log Reduction			Overall log Reduction
				30s	60s	5min	
SafeCleanse Alcohol Gel	4037/01	C. albicans ATCC 10231	4.0x 10 <sup>7</sup>	7	Na	Na	7
		A. niger NCPF 2275	2.3x10 <sup>7</sup>	4	Na	Na	4
		B. cereus NCTC 7461	5.0x10 <sup>7</sup>	Na	2	2	2

<sup>1</sup> Alcohol and triclosan. <sup>2</sup> Effective biocidal action against gram-positive and gram-negative vegetative bacteria, including multidrug-resistant pathogens (e.g., MRSA and VRE), Mycobacterium tuberculosis, and various fungi, many viruses (e.g., herpes simplex virus, human immunodeficiency virus [HIV], influenza virus (H5N1), respiratory syncytial virus, and vaccinia virus.) and Hepatitis B and C. <sup>3</sup> Biocidal efficiency is 99.99% kill (log 4 reduction). <sup>4</sup> Slightly different formulation due to different permitted ingredients between USA & EU.

# Frequently Asked Questions

## What is SafeCleanse's™ patented PA Dispersion Technology?

The relevant patents describe a combination of a 'Poli Aphron Dispersion' and water containing a high level of alcohol. The technology enables high levels of incompatible materials such as alcohols and lipids to be combined into a stable emulsion whilst using significantly lower levels of surfactants than conventional products

## How does the PA Dispersion Technology work?

1. SafeCleanse™ is formulated using technology that enables large amounts of alcohol to be added to water without causing the gel to become unstable and is the subject of the second patent.
2. SafeCleanse™ works by having the optimum level of alcohol ('ethyl alcohol' or 'ethanol'), which is lethal to viruses and microorganisms, it also contains Triclosan' as a secondary antiseptic agent, which prevents re-infection between applications. Alcohols are the most effective agent known for killing viruses and micro organisms outside the body.
3. The PA Dispersion Technology leaves intact the skin lipids that alcohol normally strips from the skin and so does not harm the skin by drying it out.
4. The PA Dispersion Technology uses very low levels of surfactants.

## How does this technology improve the product performance?

The PA Dispersion Technology allows SafeCleanse™ to use high levels of alcohol combined with other Biocides, silicones and lipids, which enables SafeCleanse™ gel :-

- to kill up to 90% of the viral infection within 30 seconds and >4.00—log10 TCID50/ml (99.99%) within 5 minutes.
- not strip the skins lipids and making it pleasant to use ensuring that user compliance is high, and further reducing the risk of user to user transmission.

## Why does SafeCleanse™ not damage the skin?

SafeCleanse™ contains alcohol, silicone and additional moisturising lipids – so the beneficial effects of alcohol are combined with very effective skin moisturising lipids and silicones to leave the skin feeling soft and moisturised without stickiness or oiliness, as well as being effectively sanitised with optimum levels of alcohol.

## Why is moisturisation important?

Good after-and in-use feel of the product is vital for compliance with the need to use the product frequently during the course of the working day in hospitals and the workplace.

## How long before re-infection occurs?

SafeCleanse™ has been specifically tested for re-infection

time and prevents re-infection for up to 3 hours after use.

## What is the significance of low levels of surfactants?

Surfactants are needed to prevent emulsions breaking up and allowing tiny droplets of oil to join up to form an oily layer floating on top of the water. The SafeCleanse™ PA Dispersion Technology enable the use a tiny fraction (about 2%) of the concentration normally needed, making the surfactants and alcohol in SafeCleanse™ less damaging to healthy skin than otherwise possible.

## What is the benefit of a Low pH?

The natural pH of skin is low (slightly acid). High pH, such as is found in toilet soap, has an irritating and drying effect on skin. The SafeCleanse™ pH is designed to mimic the acidity of skin.

## What is the benefit of having silicones in the formula?

Silicones contribute to the much-liked smooth after use feel of the skin. It is not possible to combine silicones with high levels of alcohol using any other technology.

## What do users of SafeCleanse™ think about the product feel?

All subjects liked the feel and fragrance of the product, their general comments were: "It rubs into the hands quickly"... "It feels silky"... "It smells nice"... "It's not sticky"

**Why is there a low risk of resistance developing?** Due to the use of alcohol and action of SafeCleanse™, organisms are eradicated in such a way that they appear not to develop any resistance.

## Is SafeCleanse™ toxic?

SafeCleanse™ uses very low toxicity biocides and as such the product is proven as safe to use on humans and in contact with foods and plants, and does not leave a toxic residue.

## Is SafeCleanse™ Easy to use?

SafeCleanse™ is simple to apply and no training or special safety precautions are required. Product can be applied in a variety of ways depending on the application and customer requirements.

## Is SafeCleanse™ environmentally friendly?

SafeCleanse™ is fully biodegradable.

## Why does SafeCleanse™ only contain 61 % alcohol?

The PA Dispersion Technology enables a lower concentration of alcohol to be used whilst achieving the optimum killing level (61 % compared to a typical 80% alcohol content) enabling a high frequency of use without damaging the skin (Maximum Kill, Optimum Alcohol).