



# CHLORASCRUB™ CLINICAL STUDIES

## In-Vitro Studies

Chlorascrub™ meets the requirements of the FDA's Tentative Final Monograph for Healthcare Antiseptic Drug Products. The following *in-vitro* studies were performed to assess the antimicrobial activity of Chlorascrub™:

### **1. Time Kill Study**

A time kill study was conducted to evaluate the efficacy of Chlorascrub™ against the following bacteria:

Staphylococcus aureus (2 strains tested)  
Staphylococcus epidermidis  
Micrococcus luteus  
Enterococcus faecalis  
Escherichia coli (2 strains tested)  
Pseudomonas aeruginosa (2 strains tested)  
Serratia marcescens

At a 1:10 dilution, Chlorascrub™ reduced the bacterial count by more than 99.9% in less than 3 minutes. The majority of the strains were killed immediately upon exposure to Chlorascrub™.<sup>1</sup>



# CHLORASCRUB™ CLINICAL STUDIES

## 2. Minimum Inhibitory Concentration (MIC) Study

A MIC study was conducted to assess the *in-vitro* efficacy of Chlorascrub™ against 1104 microorganisms. 1083 (98.1%) of the 1104 organisms tested, were inhibited by  $\leq 50$   $\mu\text{g/ml}$  of Chlorascrub™ solution. A concentration of 50  $\mu\text{g/ml}$  represents a 1:630 dilution of the 3.15% (w/v) topical solution. Therefore, Chlorascrub™ was effective against all the microorganisms listed in Table 2, including antibiotic resistant strains. Detailed results are presented in Table 2.

### LIST OF ORGANISMS TESTED SUSCEPTIBLE TO CHLORASCRUB™

TABLE 2

Species	Number of Strains	Minimum ( $\mu\text{g/ml}$ )	Maximum ( $\mu\text{g/ml}$ )	MIC <sub>50</sub> * ( $\mu\text{g/ml}$ )	MIC <sub>90</sub> * ( $\mu\text{g/ml}$ )
<b>All Aerobic Strains Combined</b>	896	0.20	200	16	64
<b>All Gram-Negative Aerobic Strains Combined</b>	448	0.78	200	32	64
<b>All Gram-Positive Aerobic Strains Combined</b>	448	0.20	100	8	16
<i>A. ANITRATUS</i>	17	6.25	50	16	32
<i>A. BAUMANNII</i>	28	6.25	50	32	64
<i>A. LWOFFII</i>	4	6.25	25	N.A.	N.A.
<i>B. CEPACIA</i>	21	12.50	200	64	128
<i>E. AEROGENES</i>	26	25	50	32	64
<i>E. CLOACAE</i>	26	0.78	50	32	64
<i>E. COLI</i>	51	0.78	13	4	4
<i>E. COLI ESBL+</i>	6	1.56	25	N.A.	N.A.
<i>E. FAECALIS, VANCO RESISTANT</i>	23	6.25	25	16	32
<i>E. FAECALIS, VANCO SENSITIVE</i>	31	3.13	25	16	16
<i>E. FAECIUM, VANCO RESISTANT</i>	26	3.13	13	8	8
<i>E. FAECIUM, VANCO SENSITIVE</i>	26	0.78	13	8	16
<i>E. HIRAE</i>	1	6.25	6	N.A.	N.A.
<i>H. INFLUENZAE B-LACTAMASE NEGATIVE</i>	28	6.25	25	16	32
<i>H. INFLUENZAE B-LACTAMASE POSITIVE</i>	28	6.25	50	16	32
<i>K. OXYTOCA</i>	11	12.50	50	32	64
<i>K. OXYTOCA-ESBL+</i>	5	6.25	50	N.A.	N.A.
<i>K. PNEUMONIAE</i>	16	6.25	50	32	64
<i>K. PNEUMONIAE-ESBL+</i>	5	6.25	25	N.A.	N.A.
<i>M. LUTEUS</i>	3	0.78	2	N.A.	N.A.
<i>P. AERUGINOSA</i>	36	6.25	50	32	32
<i>P. AERUGINOSA, Cipro-R</i>	15	25	50	32	64



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<i>P. MIRABILIS</i>	36	6.25	100	32	64
<i>P. VULGARIS</i>	16	12.50	50	32	64
<i>S. AGALACTIAE</i>	53	1.56	13	8	8
<i>S. AUREUS, METHICILLIN RESISTANT</i>	53	0.78	6	4	8
<i>S. AUREUS, METHICILLIN SUSCEPTIBLE</i>	53	0.78	6	4	4
<i>S. EPIDERMIDIS, METHICILLIN RESISTANT</i>	13	1.56	6	4	8
<i>S. EPIDERMIDIS, METHICILLIN SUSCEPTIBLE</i>	16	1.56	6	4	4
<i>S. HAEMOLYTICUS, METHICILLIN RESISTANT</i>	21	0.78	6	4	8
<i>S. HAEMOLYTICUS, METHICILLIN SENSITIVE</i>	7	0.78	3	N.A.	N.A.
<i>S. HOMINIS</i>	5	0.78	2	N.A.	N.A.
<i>S. MALTOPHILIA</i>	21	0.78	100	64	64
<i>S. MARCESCENS</i>	51	3.13	100	64	64
<i>S. PNEUMONIAE PEN INTERMEDIATE</i>	17	12.50	100	32	128
<i>S. PNEUMONIAE PEN RESISTANT</i>	17	12.50	100	64	64
<i>S. PNEUMONIAE PEN SENSITIVE</i>	22	1.56	50	16	64
<i>S. PYOGENES</i>	51	0.20	6	4	8
<i>S. SAPROPHYTICUS</i>	11	0.20	2	1	1

Anaerobic Species					
<b>All Anaerobic Strains Combined</b>	99	0.78	200	16	32
<i>B. FRAGILIS</i>	55	6.25	200	16	32
<i>B. THETAOTAOMICRON</i>	19	6.25	200	16	>35
<i>BACTEROIDES SPP.</i>	13	6.25	100	16	32
<i>P. BIVIA</i>	11	0.78	13	8	8
<i>E. LENTUM</i>	1	25	25	N.A.	N.A.

Yeast Species					
<b>All Yeast Strains Combined</b>	109	3.13	50	16	32
<i>C. ALBICANS</i>	57	3.13	25	32	32
<i>C. KRUSEI</i>	17	6.25	50	16	32
<i>C. PARAPSILOSIS</i>	19	6.25	50	16	64
<i>C. TROPICALIS</i>	16	6.25	13	16	16

**Total Number of Strains 1104**

\*Actual MICs were rounded up to nearest 2 log<sub>10</sub> dilution for calculating MIC<sub>50</sub> and MIC<sub>90</sub>.



# CHLORASCRUB™ CLINICAL STUDIES

## Resistance Development

The Chlorascrub™ MIC study above shows that 98.1% of the 1104 organisms tested,<sup>2</sup> were inhibited by  $\leq 50$   $\mu\text{g/ml}$  of Chlorascrub™ solution. The tested pathogens included several antibiotic resistant strains. The concentration of Chlorhexidine in Chlorascrub™ is 31 500  $\mu\text{g/ml}$ , thereby far exceeding the 50  $\mu\text{g/ml}$  concentration.

Acquired resistance to Chlorhexidine is rare and has only been found when diluted aqueous solutions have been used for disinfection.<sup>3</sup> When used undiluted and as directed, Chlorascrub™ with its 3.15% (w/v) CHG and 70% (v/v) IPA concentrations is expected to be highly effective against most pathogens, including antibiotic resistant microorganisms.

Literature reports indicate that there is no evidence of increased resistance development after prolonged and extensive use of Chlorhexidine in clinical use concentrations.<sup>4</sup>

### REFERENCES

1. Data on file. Les Entreprises Solumed, Inc. Laval, Quebec, Canada.
2. Data on file. Les Entreprises Solumed, Inc. Laval, Quebec, Canada.
3. Maki DG, Ringer M, Alvarado CJ. Prospective randomized trial of povidone-iodine, alcohol, and Chlorhexidine for prevention of infection associated with central venous and arterial catheters. *Lancet*. 1991;338:339-343.
4. Denton GW. Chlorhexidine. In: Block SS, ed. *Disinfection, Sterilization, and Preservation*; 5<sup>th</sup> ed. Philadelphia: Lippincott Williams & Wilkins; 2001:321-336.



# CHLORASCRUB™ CLINICAL STUDIES

## Summary of Clinical Study Results

This brief summary explains the key results of the Chlorascrub™ clinical studies.

Chlorascrub™ Swabs reduce the microbial count on the forearm by greater than 2 Log<sub>10</sub> 30 seconds after application. The greater than 2 Log<sub>10</sub> reduction is maintained for at least 24 hours.

Chlorascrub™ Swabsticks and Maxi Swabsticks reduce the microbial count on the abdomen by greater than 2 Log<sub>10</sub> 30 seconds after application. After 24 hours the microbial count reduction has increased to greater than 3 Log<sub>10</sub>. These results confirm the rapid-acting, effective and persistent antimicrobial activity of Chlorascrub™ on a dry site.

Chlorascrub™ Swabsticks and Maxi Swabsticks reduce the microbial count on the groin by greater than 3 Log<sub>10</sub> 1 minute after application. The greater than 3 Log<sub>10</sub> reduction is maintained for at least 24 hours. These results confirm the rapid-acting, effective and persistent antimicrobial activity of Chlorascrub™ on a wet site.



# CHLORASCRUB™ CLINICAL STUDIES

## Clinical Studies

### 1. Efficacy and Safety Study: Comparison to IPA and 4% CHG

A study was conducted to evaluate and compare the immediate and persistent antimicrobial activity of Chlorascrub™ 3.15% (w/v) Chlorhexidine Gluconate with 70% (v/v) Isopropyl Alcohol, 70% (v/v) Isopropyl Alcohol (active vehicle) and Hibiclens® (4% Chlorhexidine Gluconate, reference product) when used as an antimicrobial skin preparation prior to surgery or injection.<sup>1</sup> In addition, this randomized, parallel-group study evaluated and compared the safety of the products.

#### Methods

Healthy subjects of mixed age, gender, and race between 18 and 70 years of age, and with no evidence of dermatoses, inflammation or injury to the treatment areas were enrolled in the study. The skin preparations were tested on the forearm, on the abdomen, and in the groin (inguinal region). A minimum of 81 volunteers for the inguinal and 60 volunteers for the forearm and abdominal portions were employed, using bilateral applications. Bacterial counts of the subjects in the various treatment groups did not differ significantly at baseline.

Chlorascrub™ Swabsticks and Maxi Swabsticks were tested on the abdomen and in the groin to evaluate their efficacy for pre-operative patient skin prepping. The abdominal and inguinal sites were prepped for 2 minutes, allowed to air dry for 1.5 minutes, and then evaluated at 30 seconds, 10 minutes, 6 hours, and 24 hours after skin prepping.

Chlorascrub™ Swabs were tested on the forearm to evaluate their efficacy for patient skin preparation prior to injection. The forearm sites were prepped for 15 seconds, allowed to air dry for 30 seconds and then evaluated at 30 seconds and 24 hours after prepping.

The CHG reference product was applied twice 2 minutes followed by drying with a sterile towel for all three treatment sites (manufacturer's recommendation). Application of the active vehicle (IPA) was performed identically to the Chlorascrub™ products.

The FDA Tentative Final Monograph for Healthcare Antiseptic Drug Products: Proposed Rule published in the Federal Register of June 17, 1994 requires:

- a 2 Log<sub>10</sub> reduction in CFU/cm<sup>2</sup> of skin on the abdomen and
- a 3 Log<sub>10</sub> reduction in CFU/cm<sup>2</sup> of skin on groin sites



## CHLORASCRUB™ CLINICAL STUDIES

**10 minutes** after drug application to approve a material as a **preoperative skin preparation antiseptic**. In addition, the microbial count (CFUs) from both sites must remain below the baseline CFU count for **6 hours**.

The monograph also requires a 1 Log<sub>10</sub> reduction in CFU/cm<sup>2</sup> of skin on a dry site (forearm or abdomen) **30 seconds** after application to approve an antiseptic for **pre-injection skin preparation**.

### Results

Chlorascrub™ Swabs produced a 2.70 Log<sub>10</sub> reduction on the **forearm** 30 seconds after application, therefore, exceeding the monograph requirement of 1 Log<sub>10</sub> reduction for pre-injection skin preparation. At 24 hours after application the Log<sub>10</sub> reduction was still at 2.55, confirming the persistent activity of Chlorascrub™ Swabs.

Chlorascrub™ Swabsticks and Maxi Swabsticks achieved the following microbial count reductions from average baseline on the **abdomen**:

- 2.79 Log<sub>10</sub> reduction at 30 seconds post-application
- 2.86 Log<sub>10</sub> reduction at 10 minutes post-application
- 2.83 Log<sub>10</sub> reduction at 6 hours post-application
- 3.09 Log<sub>10</sub> reduction at 24 hours post-application

Chlorascrub™ Swabsticks and Maxi Swabsticks exceeded the FDA requirements of a 1 Log<sub>10</sub> reduction at 30 seconds for pre-injection skin preparation and of a 2 Log<sub>10</sub> reduction at 10 minutes for pre-operative skin preparation on the abdomen. Chlorascrub™ reached a >2 Log<sub>10</sub> reduction on the abdomen 30 seconds after application. After 24 hours microbial counts had further decreased to a >3 Log<sub>10</sub> reduction, attesting to the persistent and residual activity of Chlorascrub™.

On the **groin**, Chlorascrub™ Swabsticks and Maxi Swabsticks were the only products tested that achieved a >3 Log<sub>10</sub> reduction at 10 minutes, 6 hours, and 24 hours post-prepping, therefore exceeding the FDA criteria. A post-application wait time of 30 seconds resulted in a 2.92 Log<sub>10</sub> reduction that was just below the 3 Log<sub>10</sub> requirement for patient pre-operative skin preparation.

Chlorascrub™ was significantly more effective than Isopropyl Alcohol alone 24 hours post-prepping. A significant difference in microbial count was detected in the inguinal and abdominal test sites (p≤0.05). Chlorascrub™ kept microbial populations at a significantly lower level than did IPA. On the IPA-prepped sites, the populations were beginning to recover to baseline levels at 24 hours after prepping, while Chlorascrub™ continued to maintain a greater than 3 log<sub>10</sub> reduction.

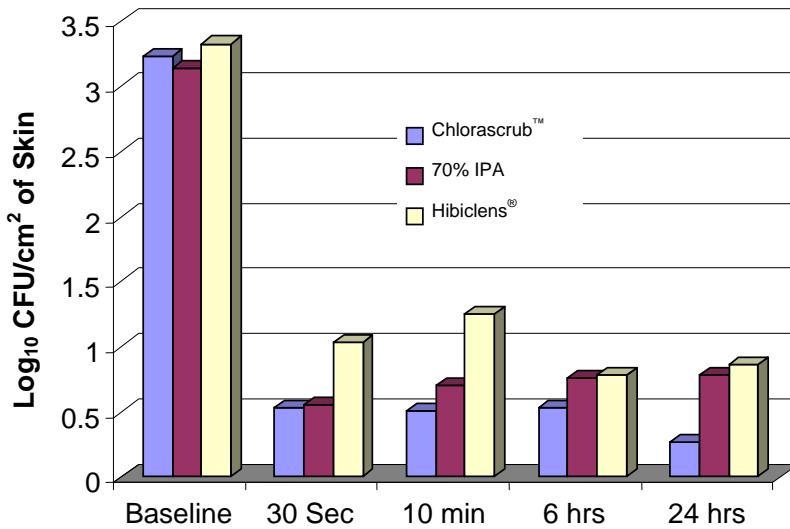


# CHLORASCRUB™ CLINICAL STUDIES

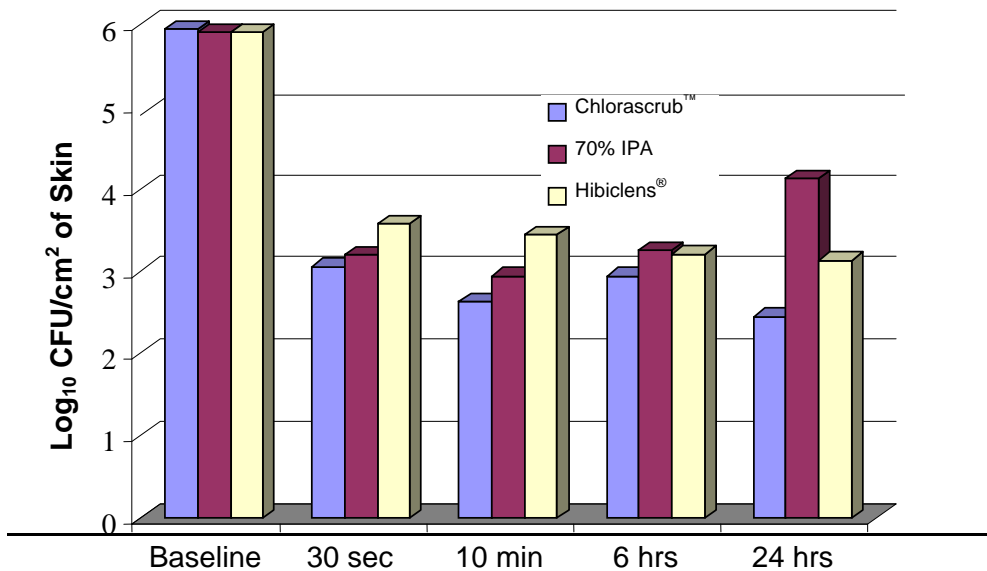
No adverse events were reported during the study. Chlorascrub™ did not demonstrate any significant skin irritating properties.

A graphic representation of the study results can be seen in the charts below:

## Microbial Counts (Abdomen)



## Microbial Counts (Groin)





## CHLORASCRUB™ CLINICAL STUDIES

### Conclusion

Chlorascrub™ was found to be safe and effective as a patient skin antimicrobial preparation for use prior to surgery and injection. Chlorascrub™ exceeds the FDA requirements in terms of wait time for full efficacy, microbial count reduction, and duration of antimicrobial activity. A microbial count reduction of 3.5 log<sub>10</sub> on the inguinal site after 24 hours verifies the product's excellent persistent activity. The >2 log<sub>10</sub> reduction on the abdomen and forearm 30 seconds after application attests to the fast and effective antimicrobial activity of Chlorascrub™.



## CHLORASCRUB™ CLINICAL STUDIES

### 2. Maxi Swabstick Efficacy Study: Comparison to IPA and 4% CHG

A study was conducted to evaluate and compare the immediate and persistent antimicrobial activity of Chlorascrub™ Maxi Swabsticks, Maxi Swabsticks Vehicle (70% (v/v) Isopropyl Alcohol), and Hibiclens® (4% (w/v) Chlorhexidine Gluconate, reference product) and to evaluate and compare the safety of all three test articles.<sup>2</sup>

#### Methods

Healthy subjects of mixed age, gender, and race between 18 and 64 years of age, and with no evidence of dermatoses, inflammation or injury to the treatment areas were enrolled in the study. Bacterial counts of the subjects in the various treatment groups did not differ significantly at baseline. All skin preparations were tested in the groin (inguinal region). The subjects were randomized and 41 inguinal areas were treated and analyzed for each test preparation.

**Chlorascrub™ Maxi Swabstick** (3.15% (w/v) CHG with 70% (v/v) IPA) was applied topically for 2 minutes over a 3 x 7.5 inch area on the groin and allowed to air dry for 1.5 minutes.

A **Maxi Swabstick** saturated with 5.0 mL of the **70% v/v IPA** was applied topically for 2 minutes over a 3 x 7.5 inch area on the groin and allowed to air dry for 1.5 minutes. The **CHG reference product** was applied topically for 2 minutes over a 3 x 7.5 inch area on the groin and dried with a sterile towel and applied for another 2 minutes and dried with another sterile towel (manufacturer's recommendation).

#### Results

The most stringent FDA requirement in the *Tentative Final Monograph for Healthcare Antiseptic Drug Products* to approve a material as a preoperative skin preparation antiseptic is that it reaches a 3 Log<sub>10</sub> reduction in microbial count (CFU)/cm<sup>2</sup> of skin on groin sites 10 minutes after drug application. In addition, the microbial count must remain below the baseline CFU count for 6 hours.

Chlorascrub™ Maxi Swabsticks demonstrated significantly better antimicrobial activity than Maxi Swabsticks Vehicle (IPA) and the CHG reference product after antiseptic application at 10 minutes, 6 hours, and 24 hours (p≤0.05).

Treatment with Chlorascrub™ Maxi Swabsticks resulted in a 3.77 Log<sub>10</sub> reduction at 10 minutes, increasing to a reduction in microbial count of 4.24 Log<sub>10</sub> after 24 hours. The Maxi Swabsticks Vehicle (IPA) also reached the 3 Log<sub>10</sub> reduction at 10 minutes but the microbial load started rising and the product was not able to maintain the 3 Log<sub>10</sub> reduction after 6 or 24 hours.



# CHLORASCRUB™ CLINICAL STUDIES

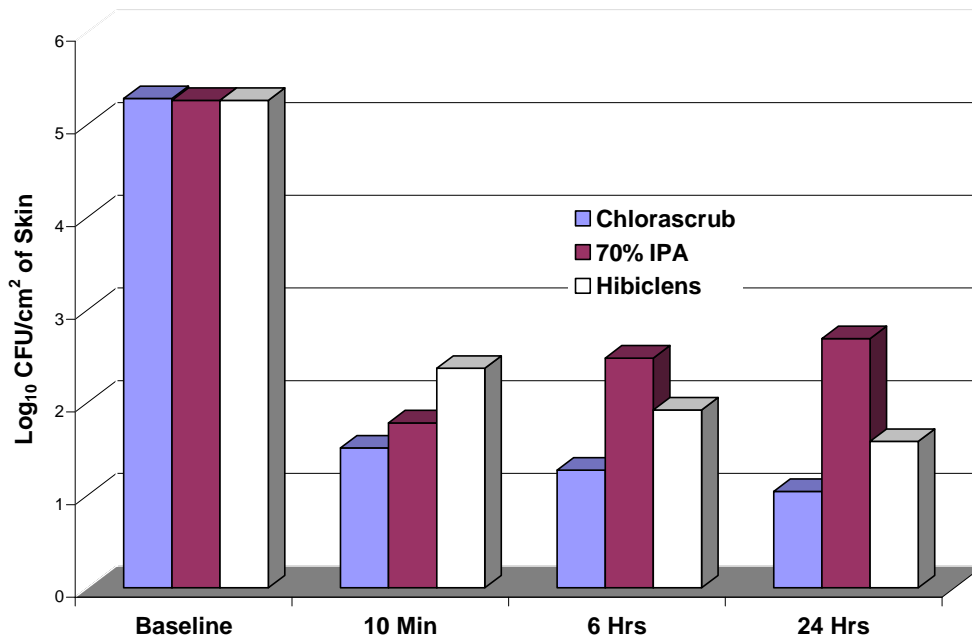
Only Chlorascrub™ Maxi Swabsticks and Maxi Swabsticks Vehicle (IPA) achieved the required 3 Log<sub>10</sub> reduction at 10 minutes. For all products, the microbial counts remained below baseline at 6 hours.

Table 3. Summary of the Log<sub>10</sub> reductions achieved on the groin sites

Product	Mean Log <sub>10</sub> Reductions from Baseline			
	N	10 Minutes	6 hours	24 hours
Chlorascrub™ Maxi Swabsticks	41	3.77	4.01	4.24
Maxi Swabsticks Vehicle (IPA)	41	3.48	2.78	2.57
CHG Reference Product	41	2.89	3.34	3.68

Figure 3

### Mean Log<sub>10</sub> CFU Counts Groin Skin



No adverse events were reported during the course of the study.



## CHLORASCRUB™ CLINICAL STUDIES

### Conclusion

Chlorascrub™ Maxi Swabsticks exceeded the FDA criteria in the groin region for patient preoperative skin preparation. Chlorascrub™ Maxi Swabsticks demonstrated significantly greater antimicrobial activity than 70% (v/v) IPA; Maxi Swabsticks and the CHG reference product after antiseptic application at 10 minutes, 6 hours and 24 hours. Microbial counts decreased over the 24-hour period, confirming the highly persistent activity of Chlorascrub™.



## CHLORASCRUB™ CLINICAL STUDIES

### 3. Efficacy Study: Evaluation of Post-Application Wait Time

The FDA Tentative Final Monograph for Healthcare Antiseptic Drug Products: Proposed Rule published in the Federal Register of June 17, 1994 requires a 3 Log<sub>10</sub> reduction in microbial count on groin sites 10 minutes after drug application to approve a material as a preoperative skin preparation antiseptic. In addition, the microbial count (CFUs) must remain below the baseline CFU count for 6 hours.

In the clinical setting it is often not desired or even possible to wait the additional 10 minutes to assure that the product reaches the required 3 Log<sub>10</sub> reduction. Therefore, this study was designed and conducted to determine the maximum wait time after application of Chlorascrub™ Maxi Swabsticks until the 3 Log<sub>10</sub> reduction is achieved on the groin skin (inguinal area).<sup>3</sup>

#### Methods

Healthy subjects of mixed age, gender, and race between 18 and 64 years of age, and with no evidence of dermatoses, inflammation or injury to the treatment areas were enrolled in the study. Sufficient subjects to reach at least 25 qualified subjects to enter the treatment phase were included in this study.

Chlorascrub™ Maxi Swabstick (5.1 mL of 3.15% (w/v) CHG and 70% (v/v) IPA) was applied topically for two minutes over a 3 x 7.5 inch area on the groin using the following technique. The Chlorascrub™ Maxi Swabstick, a flat two-sided device with a foam tip was removed from the package with sterile gloves. One of the flat sides of the foam tip of Chlorascrub™ Maxi Swabstick was placed in the center of the 3 x 7.5 inch prep area. The skin was held taut and prepped vigorously in a rapid back and forth manner for one minute. The Swab was turned over and the unused side of the foam tip was used to prep the same area. The skin was held taut and prepped vigorously in a rapid back and forth manner for one minute. The area was air dried for 1.5 minutes prior to beginning the contact time.

The inguinal sites were randomly sampled after the following post-application wait times: 30 seconds, 1, 3, 5, and 10 minutes. The technicians responsible for plating and data collection were blinded as to the post-application sample time assignment.

#### Results

Chlorascrub™ Maxi Swabsticks significantly reduced the microbial count in the groin at all time points.

Chlorascrub™ achieved a >3 Log<sub>10</sub> reduction after a wait time of one (1) minute post-application.



# CHLORASCRUB™ CLINICAL STUDIES

The mean log<sub>10</sub> reductions in CFU/cm<sup>2</sup> of groin skin are listed in Table 4 below.

Table 4. Microbial count reductions at various time points after Chlorascrub™ application in the groin

	Wait Time after Application					
	30 sec	1 min	3 min	5 min	10 min (left) <sup>a</sup>	10 min (right) <sup>b</sup>
Mean log <sub>10</sub> Reduction	2.85	3.22	3.18	3.1	3.08	3.24

<sup>a</sup>left inguinal site; <sup>b</sup>right inguinal site

## Conclusion

Chlorascrub™ reduces the microbial count on the groin by more than 3 Log<sub>10</sub> one minute after application, thus exceeding the 10 minute FDA required wait time in the groin region for a patient preoperative skin preparation drug product.

## REFERENCES

1. Data on file. Les Entreprises Solumed, Inc. Laval, Quebec, Canada.
2. Data on file. Les Entreprises Solumed, Inc. Laval, Quebec, Canada.
3. Data on file. Les Entreprises Solumed, Inc. Laval, Quebec, Canada.



# CHLORASCRUB™ CLINICAL STUDIES

## 4. 7 Day Persistence Study

Chlorascrub™ products combine the immediate antimicrobial activity of 70% (v/v) isopropyl alcohol with the persistent properties of 3.15% (w/v) chlorhexidine gluconate. This formulation results in a broad-spectrum skin antiseptic that is both fast acting and long lasting. Chlorascrub™ kills transient and resident skin microorganisms rapidly and then prevents the re-growth of microorganisms.

We recently conducted a clinical study to more thoroughly evaluate the persistent properties of Chlorascrub™ products<sup>1</sup>. The study was performed using a cross-over design that allows for exchangeability of the study results between the applicators. The treatment sites were covered with a semi-permeable dressing for the duration of the study. The results are listed in the table below:

### Mean Log<sub>10</sub> Reductions after skin preparation with Chlorascrub™ products<sup>1</sup> for pre-operative indications

Prep Time	Treatment Site	Mean Log <sub>10</sub> Reductions from Baseline		
		10 minutes	48 hours	7 days
2 min	Abdomen	2.01 (N=24)	n/a	1.76 (N=23)
2 min	Inguinal	3.29 (N=38)	3.07 (N=35)	1.51 (N=28)

### Conclusion:

The study results confirm the long-lasting antimicrobial activity of Chlorascrub™ products<sup>1</sup>. One application is sufficient to ensure that the bacterial level on the patient's skin remains low over an extended period of time. Chlorascrub™ is the first skin antiseptic product with clinically proven persistent activity of 7 days.

### NOTES

1. Study only conducted on Chlorascrub™ Swabstick and Maxi Swabstick.



## CHLORASCRUB™ CLINICAL STUDIES

### 5. Irritation Safety Study: Evaluation of a 14-day Cumulative Irritation Patch Test

A skin irritation study was conducted to evaluate Chlorascrub™ for induction of skin irritation under occlusive, semi-occlusive, and open conditions.<sup>1</sup> Thirty-one subjects completed this single-center, blinded, randomized study.

#### Methods

The subjects received applications of test solutions once a day, every day for 14 days. The test solutions applied were:

- 3.15% (w/v) Chlorhexidine Gluconate in 70% (v/v) Isopropyl Alcohol (Chlorascrub™)
- 10% aqueous povidone-iodine solution (Betadine®)
- 70% (v/v) Isopropyl Alcohol
- 4% (w/v) aqueous Chlorhexidine Gluconate (Hibiclens®)
- Sodium lauryl sulfate (positive irritant control)
- 0.9% aqueous sodium chloride (saline, negative irritant control)

All tested solutions were applied under semi-occlusive and occlusive conditions. The solutions were applied to a patch pad and allowed to dry for a maximum of 30 minutes prior to patch application to the subject. In addition, Chlorascrub™ was tested under open conditions with the solution applied and massaged into the skin for 30 seconds and allowed to air dry for 30 seconds.

#### Results

Under semi-occlusive dressing, Chlorascrub™, 70% (v/v) Isopropyl Alcohol and 4% (w/v) CHG produced irritation equivalent to saline solution (negative irritant control) and equivalent to each other. Povidone-iodine, however, produced significantly greater irritation.

Under total occlusion, both Chlorascrub™ and povidone-iodine were significantly more irritating than 70% (v/v) Isopropyl Alcohol, 4% (w/v) CHG and saline.

When Chlorascrub™ was applied without dressing, it did not produce any irritation during the 14-day testing period.

In general, all test solutions, except povidone-iodine, tended to be more irritating under occlusive conditions than under semi-occlusive conditions.

#### Conclusion

Chlorascrub™ has an irritation potential equivalent to normal saline solution when it is used under semi-occlusive conditions (clinical use conditions) for 14 days.

#### REFERENCES

1. Data on file. Les Entreprises Solumed, Inc. Laval, Quebec, Canada.



# CHLORASCRUB™ CLINICAL STUDIES

## 6. Sensitization Safety Study: Evaluation of a Repeated Insult Patch Test

A study was conducted in 210 volunteers to evaluate Chlorascrub™ for induction of contact sensitization.

### Methods

Each subject received applications of both, Chlorascrub™ (3.15% (w/v) Chlorhexidine Gluconate in 70% (v/v) Isopropyl Alcohol) and saline solution (0.9% aqueous sodium chloride). Saline served as the negative control. Chlorascrub™ was tested under semi-occlusive and saline under occlusive conditions.

The products were applied 10 times during a 23-day period (induction period), followed by a rest period, and then were applied again at day 36, 38, and 40 (challenge period).

### Results

Under the semi-occlusive conditions of this study, Chlorascrub™ did not induce any sensitization. In addition, irritation elicited by Chlorascrub™ (semi-occlusive conditions) was slightly less than that of saline solution (occlusive conditions).

### Conclusion

Chlorascrub™ does not elicit evidence of sensitization when used under semi-occlusive conditions (clinical use conditions).

### REFERENCES

1. Data on file. Les Entreprises Solumed, Inc. Laval, Quebec, Canada.