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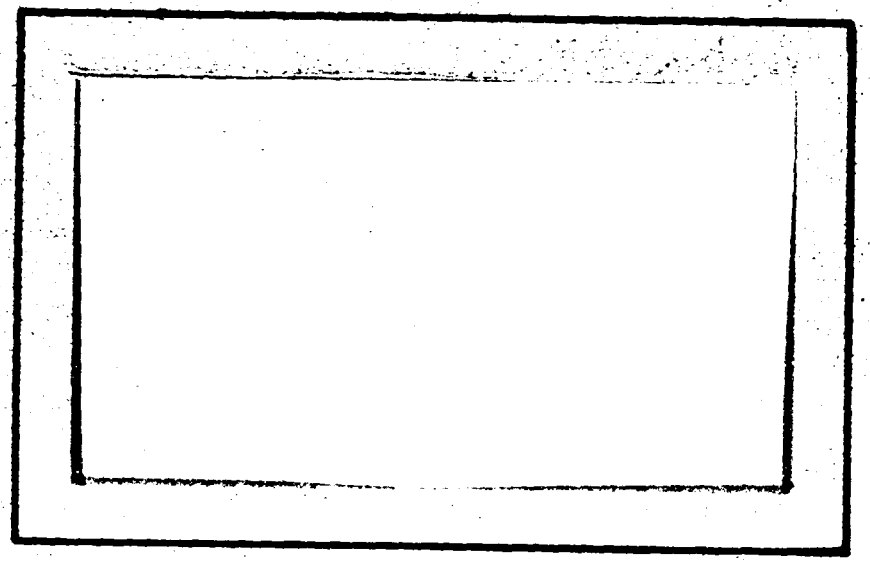

FAIRCHILD
REPUBLIC COMPANY

MS187R5003
3 October 1980

FINAL REPORT

SPACECRAFT SURGICAL SCRUB SYSTEM

Prepared for
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
LYNDON B. JOHNSON SPACE CENTER
HOUSTON, TEXAS 77058

Contract NAS9-16024

DRL Line Item No. 2

FAIRCHILD

Fairchild Republic Company Farmingdale, L.I. New York 11735

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1.0 INTRODUCTION

The object of this program was to develop a biomedical cleaning agent for pre-and-post-operative scrubs in zero-gravity aboard the Space Shuttle. This follows the previous development under contract NAS9-15698 of a non-pressurized sanitation agent foam dispenser for the WCS for Space Shuttle. In both cases there is a requirement for ease of handling and control in zero gravity and minimizing the quantity of water required. The program tasks include the selection of biocidal agent from among the variety used for surgical scrub, formulation of a dispensing system, test, and delivery of flight dispensers. Dr. H. D. Freudenthal served as a consultant.

2.0 SUMMARY

The evaluation of candidate biocidal agents led to the selection of an iodophore. The choice was based on its effectiveness on single applications, its general familiarity among surgeons, and its previous qualification for space use. The recommendation was made in MS187R5001. The delivery system was a choice between the squeeze foamer system developed for the WCS sanitation agent, and impregnated polyurethane foam pads. The impregnated foam pad was recommended because it is a simpler system since the squeeze foamer requires some applicator to effectively clean the skin surfaces, whereas the foam pad is the applicator and agent combined. However, since the squeeze foamer is to be used on Shuttle and will be familiar, both systems were carried through test and will be delivered. Testing, in accord with the procedure in MS187R5002 Rev. A, demonstrated that both systems are effective for use as surgical scrubs.

3.0 SURGICAL SCRUB SYSTEM

3.1 Biocidal Agent Selection

The more common surgical scrub systems include the following:

1. 70% alcohol.
2. Iodophores.
3. Chlorhexidine.
4. Hexachlorophene.
5. Quaternary ammonium compounds.

In the trade study, MS187R5001, it was concluded that alcohol was not suitable for zero-gravity use, that hexachlorophene should not be considered since it is not completely effective with a single use, and that the quaternary ammonium compounds should be discarded since they are only weekly bacteriocidal.

In deciding between an iodophore and chlorhexidine, both effective agents, the iodophore was chosen on the basis of its greater familiarity to surgeons in this country, and its use on previous manned space missions. Betadine, the brandname of Purdue Frederick Co. was selected. It is available as Betadine Surgical Scrub, and to reduce the detergent concentration somewhat without reducing the available iodine concentration, it was mixed with Betadine Solution. The control of detergent concentration is required to achieve a suitable viscosity for the squeeze foamer and to control the foam quantity when used with the polyurethane pads.

3.2 Dispenser Selection

In the previous study, a squeeze foamer, P/N ESK1008-1, was developed. In this dispenser, the detergent solution is placed in a flexible polyethylene bottle, which also contains an inflatable airbag. When the bottle is squeezed the solution and air are simultaneously forced through a porous glass plug to produce a foam. When the bottle relaxes air is drawn into the airbag past a check valve and the cycle may be repeated.

To effectively scrub the hands an applicator is required which provides some abrasive action. Typically in conventional scrubbing a nylon bristle brush is used. It was felt that this might cause some undesirable spatter. A substitute could be a moderately coarse sponge pad.

A second approach suggested in the proposal is the use of an impregnated flexible foam pad. This technique was suggested by an article in "Design News", 4/23/79 reporting on the use by Tenneco Chemicals Foam Division of polyurethane pads for a variety of personal hygiene applications. This approach has the advantage of providing both the agent and applicator in one unit. For increased versatility, a composite pad of two porosities and hence coarseness, were fabricated. The coarse side of the pad is used on the fingers and softer side on the arms. Because of this simplicity,

the impregnated pad was recommended. However, testing of both dispensers continued and are supplied to NASA for evaluation.

3.3 Manufacture

3.3.1 Squeeze Bottle

The compounding of a suitable solution depends on achieving a suitable viscosity to develop a good foam. The original recommendation was a mixture of 40% Betadine Surgical Scrub and 60% Betadine Solution. Further testing has modified this slightly to produce a better foam quality. The new recommendation is:

30% Betadine Surgical Scrub
45% Betadine Solution
25% Water

To load the bottle, the foamer and airbag assembly is removed from the bottle and up to 115 ml of solution is added. The airbag is re-inserted and the foamer is snapped in place. The cap is added to complete the process. With the bottle in the upright position and the lid open, the bottle is squeezed to expel air from the bottle through the porous foamer. Relaxing the squeeze allows air to fill the airbag through a check valve. The foamer is now ready for use by inverting the bottle and squeezing. In zero-gravity the solution is always in contact with the porous foamer and is used in any position.

3.3.2 Impregnated Polyurethane Pad

The foams selected were manufactured by Tenneco Chemicals Foam Division. They are Tenneco 4666V 30 ppi
6210 60 ppi

Both porosities were procured as ½" sheets. They were bonded together with 3M contact cement 1357. The cement was spread on a sheet of waxed paper with a card and the foam pads lightly placed on the adhesive film and removed. The foam picked up a uniform, but not continuous coating so that it remains porous. When the adhesive is tack-free, the two pads are brought together and a firm bond produced. The one inch thick composite is then cut with an electric knife in rectangles 3½ X 2½ inches.

The pads are sealed in a vapor barrier film, MIL-B-131F, Class 1. Ludlow

Corp. Marvelseal 360 was used. This is a lamination of nylon film, aluminum foil and polyethylene. A sheet of film about 8 X 6 inches is folded in half (formed 4 X 6 inch halves) and two of the three open sides are sealed with a bar heat sealer. The pad is inserted and biocide solution is introduced with a syringe. The remaining open side is then sealed.

The Betadine mixture was modified by the addition of water to make it less dry. It contains:

30 parts Betadine Scrub
45 parts Betadine Solution
35 parts Water.

7.5 ml of this mixture was used in the testing. It was felt that perhaps 10 ml would be better.

3.4 Use

For both systems, the hands and arms are first wet with water either by a hand washer or wet sponges. For the squeeze bottle, about five squeezes is sufficient to get a good lather started. A foam pad is used to properly scrub the skin. Additional foam may be used as desired. With the impregnated pad, simply rubbing with the moistened skin is sufficient to develop a lather.

With both systems it is desirable to have a nail cleaner to get at the region under the fingernails. A small orange-wood stick, pointed at one end and with a chisel edge at the other was used in testing and will be supplied in the package with the pad.

After three minutes of diligent scrubbing the foam is removed with a series of sterile wipes. A high wet-strength wipe manufactured by the Scott Paper Co., Brand 570-0 was used. This was cut down to 9 X 12 inch sheets which were folded in a vellum wrapper and packaged in the barrier foil with about 10 ml of water per sheet, and heat sterilized. The packages could be sterilized in an autoclave but the high temperature wrinkled the package. It was consequently steamed at 1 atmosphere for 90 minutes on three consecutive days and then sealed. To produce dry wipes the packages were placed in an oven at 110^{o}C to drive off moisture and then sealed. The sequence used was to start with dry wipes to remove the bulk of the foam, then wet wipes to

remove stickiness and finally if desired a dry wipe to finish. It would be logistically simpler to supply only wet wipes at some intermediate moisture level and air dry the hands.

Following removal of the foam, a new pad or additional foam from the squeeze foamer is used to repeat the scrub procedure. Following the wipes the user is ready to glove.

4.0 TEST RESULTS

The test procedure MS187R5003 is given in Appendix A.

4.1 Environmental Exposure

Two squeeze bottles and ten impreganted pads were placed in a 120°F oven for 24 hours. The impregnated pad packages were just slightly turgid while warm but otherwise there was no apparent change. There was no weight loss by any package.

4.2 Microbiological Test

Two skin samplings were made before and after scrubbing. One sampling, using a moistened swab, probed one finger tip to the first joint repeatedly, including the finger nail, cuticle and part of the underside of the nail. The area covered was estimated at 15 cm^2 for male subjects and 12 cm^2 for female subjects. The second sampling was of a portion of the palm and of the arm for a total area of about 25 cm^2. Again the swab was wiped repeatedly over the area. The results of colony counts after culturing for 48 hours at 37.5°C are given in Table I.

In only one case was sterility achieve. In this case, the pre-scrub count was low and the results may be attributed to the fact that the subject had had contact with the biocide 24 hours previously.

Two samples are higher than the success criterion of less than 5 organisms per square centimeter. In one case, the subject, a female, had fingernails somewhat longer than desirable which may have hindered scrubbing. The other case had the highest pre-scrub count. The probing at the fingernail region may have been too vigorous. The sampling from the palm and arm regions showed no organisms in 5 subjects. This region also had a significantly lower count than the finger region in the pre-wash sampling.

There was no significant difference between the results between the squeeze bottle or the impregnated pad although the impreganted pad results were somewhat lower. Aside from the one case mentioned earlier, there is no significant difference between male and female subjects.

On the whole, the results are satisfactory. It is likely that when the scrub system is used by professionals with experience in proper scrubbing techniques, that the results will be better.

TABLE I - MICROBIOLOGICAL RESULTS

SYSTEM	SEX	PRE-SCRUB				POST-SCRUB			
		FINGER		ARM		FINGER		ARM	
		COLONIES	COL/CM^2	COLONIES	COL/CM^2	COLONIES	COL/CM^2	COLONIES	COL/CM^2
Squeeze Bottle	M	1930	129	84	3.4	37	2.5	2	0.1
"	F	6230	519	260	10.4	292	24.3	0	0
"	M	725	48	65	2.6	4	0.3	3	0.1
"	F	3440	287	125	5.0	51	4.3	0	0
Impreg. Pad	F	5580	465	285	11.4	23	1.9	0	0
"	M	6710	447	53	2.1	116	7.7	6	0.2
"	F	2130	178	190	7.6	21	1.8	0	0
"	M	295	20	18	0.7	0	0	0	0

AREA FINGER TIP; MALE 15 CM^2, FEMALE 12 CM^2

AREA, ARM AND PALM; 25 CM^2

FAIRCHILD
REPUBLIC COMPANY
MS187R5003
3 October 1980

APPENDIX A

MS187R5002
3 August 1980
REV. A 22 August 1980
REV. B 3 October 1980

TEST PLAN
SPACECRAFT SURGICAL SCRUB SYSTEM

Prepared for

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

LYNDON B. JOHNSON SPACE CENTER
HOUSTON, TEXAS 77058

Contract NAS9-16024
DRL Line Item No. 3

FAIRCHILD

Fairchild Republic Company Farmingdale, L.I. New York 11735

Prepared by: M Abbate
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MS187R5002
3 August 1980
Rev. A 22 August 1980
Rev. B 3 October 1980

1.0 PURPOSE

These tests are designed to evaluate the effectiveness of a surgical cleansing agent formulated for use in the zero-g environment of the Space Shuttle. It assumes that only small quantities of water are available and that the scrub occurs in the open cabin rather than in an enclosure. The surgical scrub system will be exposed to an elevated temperature environment and then tested microbiologically.

2.0 SURGICAL SCRUB SYSTEM

The surgical scrub system will consist of polyurethane foam pads impregnated with an iodophore and encapsulated in a water vapor barrier foil package. The foam pad will consist of a lamination of two different foam sheets, each one-half inch thick forming a composite 2½" x 3½" x 1" thick. One foam sheet will have 30 pores per lineal inch, the other 60 ppi. The active agent will be 5 ml of a mixture of 40% Betadine Surgical Scrub and 60% Betadine Solution. The package will be made of a heat sealable foil in accordance with MIL-B-131. A nail cleaner will be available with the pad. Sterile paper wipes will be available for removal of the soap foam generated during the scrub.

In addition, a surgical scrub system using the squeeze foamer dispenser will be tested. The dispenser, P/N ESK 1008-1, will be filled with a mixture of 40% Betadine Surgical Scrub and 60% Betadine Solution. A polyurethane foam pad, without impregnants, will be used to assist scrubbing.

3.0 ENVIRONMENTAL EXPOSURE

The surgical scrub packages will be exposed to a temperature of 120°F for 24 hours simulating temperatures incident to shipping or storage. The packages will be examined for delamination and leakage along the heat sealed edges, or for other damage. The packages will be weighed to determine weight loss.

4.0 TEST PROCEDURE

4.1 Test Subjects

The test will be conducted with four male and four female subjects. Each must have well trimmed fingernails and healthy cuticles. No open lesions may exist on any portion of the test skin surface (fingers, hands, lower arms). Three subjects will use the impregnated polyurethane foam pad system,

and three will use the squeeze foamer system. The scrub effect should be basically identical.

4.2 Scrubbing Procedure

4.2.1 Impregnated Polyurethane Foam Pad

a. Thoroughly wet, the test skin surface with either pre-moistened wet wipe or with tap water.

b. Open one surgical scrub package and remove the impregnated pad. For a period of not less than three minutes scrub first one hand then the other as follows:
   1. Stroke each side of each finger ten times.
   2. Stroke across finger tips, nails and cuticles 20 times.
   3. Stroke palm and back of hand ten times.
   4. Stroke each side of lower arm to elbow ten times.
   5. Using the nail cleaner, clean under nails.

c. Using three sterile wet wipes, wipe the surgical agent off the hands, starting with the fingers and working toward the elbows.

d. Open a new surgical scrub package and repeat step b.

e. Repeat step c using as many wipes as required to remove foam. Hands are now cleaned and should not touch any non-sterile surfaces.

f. Dry skin with a sterile dry wipe.

4.2.2 Foam Squeezer

The scrubbing procedure is essentially the same as in 4.2.1 with the exception that in step b and d, the biocidal agent will be dispensed with the squeeze foamer in sufficient quantity (number of squeezes) to adequately cover the skin surfaces. This should require no more than 5 squeezes but is a matter of preference by the individual.

4.3 Microbiological Testing

The test will measure the removable bacteria on surfaces of the hands and arms before and after the surgical scrub.

a. Swab the skin surface of nominally clean hands and arms with a swab moistened with sterile water. Include portions of the hand

and arm surfaces and particularly the fingernail region at the junction of fingernail and skin, and the cuticles. The swabbing should not be too vigorous or probe fingernail region crevices excessively so as to dislodge materials. Estimate the area swabbed from the total stroke length and swab contact length. Take two swab sample per subject.

b. Immerse and agitate the swab in trypticase soy broth containing sodium thiosulfate inhibitor. Dilute the broth as required, plate the broth, culture, and record the number of colonies.

c. Perform surgical scrub in accordance with paragraph 4.2.

d. Repeat testing procedure, paragraph 4.3.a and b. Record the number of colonies.

4.4 Criterion for Success

The goal of the scrub is sterility. However, the scrub shall be considered successful if the bacteria count does not exceed five (5) organisms per square centimeter of skin area.