NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

Technical Report 32-1160

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Prepared Under Contract No. NAS 7-100
National Aeronautics & Space Administration

Acknowledgment

This report was prepared for the benefit of the Materials Section of the Jet Propulsion Laboratory; Mr. Hugh G. Maxwell was cognizant engineer. We are indebted to Mr. Andrew G. Young for performing the electrical tests.

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Abstract

The effects of sterilization conditions on a number of products of interest in spacecraft applications are discussed. After classification according to function, the products were subjected to the type approval decontamination and dry heat sterilization procedures of the Jet Propulsion Laboratory (JPL) consisting of (1) exposure to ethylene oxide–Freon 12 for six cycles of 28 h each at 50°C and 50% relative humidity; and (2) exposure to dry heat for six cycles of 92 h each at 135°C in dry nitrogen. Extensive testing was performed both before and after exposure to ethylene oxide, and again after dry heat exposure, to determine the changes in the physical, mechanical and electrical properties of the products.

The criteria used for rating the compatibility of the products tested with the sterilization environments are presented.

Some of the products were also exposed, after ethylene oxide decontamination, to 120°C in nitrogen for six cycles of 250 h each and to 150°C in nitrogen for six cycles of 59 h each. These results are also discussed.

Effects of Ethylene Oxide—Freon 12 Decontamination and Dry Heat Sterilization Procedures on Polymeric Products

I. Introduction

The effects of sterilization environments on polymeric products are under study. In a previous JPL report (Ref. 1) the effects of dry heat sterilization at 145°C on 160 different commercial products were discussed. The present report concerns the effects of both ethylene oxide (ETO) decontamination and dry heat sterilization conditions on a smaller number of products of interest in spacecraft applications. The overall objective of these investigations is to aid the selection of those polymeric products that can be used on sterilized, planetary landing capsules.

The ETO decontamination, as well as the dry heat sterilization procedures employed during the present study, was in accordance with the JPL environmental specification VOL-50503-ETS, type approval testing, details of which are given in *Experimental Section* of this report.

As in the previous study (Ref. 1), the candidate products were classified into categories according to their functions, such as adhesives, encapsulants, tapes, and so forth. Pertinent tests were then assigned to each category. The tests were performed on individual samples before exposure, after exposure to the gaseous decontamination environment and again after exposure to dry heat sterilization at 135°C in an atmosphere of nitrogen (Fig. 1). The changes in the properties of the products after the dry heat exposure were assessed and compatibility ratings were assigned to each product.

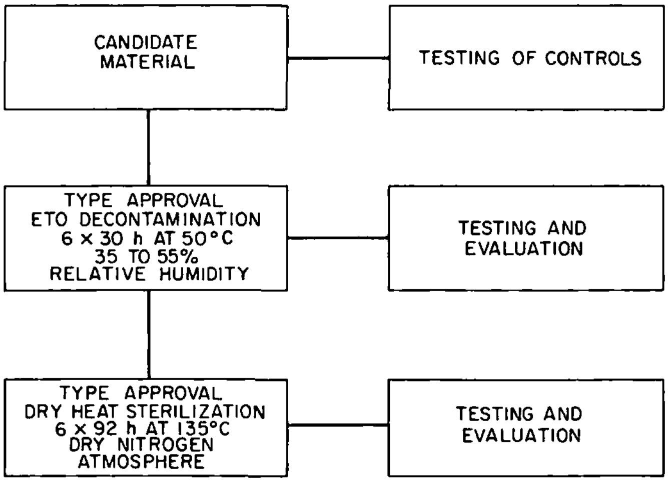

Fig. 1. Type approval test program

The criteria for these ratings were based on a required performance of each class of products. They are intended to be a guide, rather than a final judgment, to the sterilizability of the products tested.

Heat sterilization is time-dependent as well as temperature-dependent. The so-called *D-value*, the time necessary to kill 90% (or 1 log value) of any spore population, is small at high temperatures, and larger at lower temperatures (Ref. 2). Sterilization temperatures that are justifiable or acceptable range from 105–160°C.[1]

In order to study the effects of other sterilization temperatures on properties, five of the products were also exposed to 120 and 150°C after ETO decontamination. Test results are discussed in Section IV-C.

II. Plan of Report

This report is divided into two main parts: the text proper and the appendixes. The text provides summarized test results in tabular form for each class of product after ETO exposure and after ETO–dry heat exposure. The latter tables contain the compatibility ratings. To supplement the general discussion, other tables and graphic representations are also given in the text. Materials, procedures and tests are all discussed in Section III.

Details of the ETO and dry heat exposure test results are found in Appendix A. Appendix B consists of the detailed test results for the five products exposed to dry heat at 120 and 150°C. Appendix C contains information about those products that required preparatory treatment before their use as test samples. Mixing ratios, pot lives, and cure conditions are the kinds of information included in this Appendix.

III. Experimental Section

A. Sample Materials and Preparation for Testing

The products tested during this report period were mostly proprietary, but the nature of the basic polymeric constituent was known. For each product, the constituent polymeric material is shown in the summary tables.

[1]Personal communication from Carl W. Bruch, National Aeronautics and Space Administration.

Test specimens were prepared in accordance with the sizes and shapes specified in the standard test methods used.

Some of the products, particularly the adhesives and encapsulants, required such preliminary handling as mixing and degassing before castings or test specimens could be prepared. The films, elastomers, plastics, tapes and wire coatings were obtained ready for use.

The adhesives, the coatings and the tapes were applied to 2024-T3 unclad aluminum panels, 0.064 in. thick. The panels were first degreased repeatedly with acetone and then deoxidized by immersion in an aqueous solution of Oakite 164 at 180°F, for 8 to 12 min. They were used for bonding within 4 to 6 h after rinsing and oven-drying at 150°F.

Both control and exposed test specimens were conditioned at constant temperature (75 ±2°F) and constant relative humidity (50 ±2%), before testing.

B. Test Equipment

Standard equipment was used in most cases and needs no description. Special test equipment included the following: (1) the ETO–Freon 12 decontamination setup; (2) the dry heat sterilization equipment; and (3) a creep test apparatus.

1. Description of the ETO–Freon 12 decontamination setup. The automatic ethylene oxide decontamination apparatus used in this study was described previously (Ref. 3). However, a modification to the original design has since been necessary. In the original apparatus, the humidification of the sterilant gas was achieved by passing it through a "bubbler" type chamber. It was found, however, that the ETO component of the mixture combines with the water and changes the composition of the mixture. Therefore, a direct steam injector was designed and incorporated into the basic system. Figure 2 is the schematic of the modified apparatus. Distilled water, under air pressure, is forced into a filament-heated stainless steel chamber and immediately vaporized. As soon as a quantity of vapor is formed, it is carried into the ETO–Freon 12 gas stream by means of an aspirator. The humidity solenoid valve of the earlier design is now located in the tube carrying liquid water to the steam chamber. Its control by the humidity controller remains unchanged (Fig. 3).

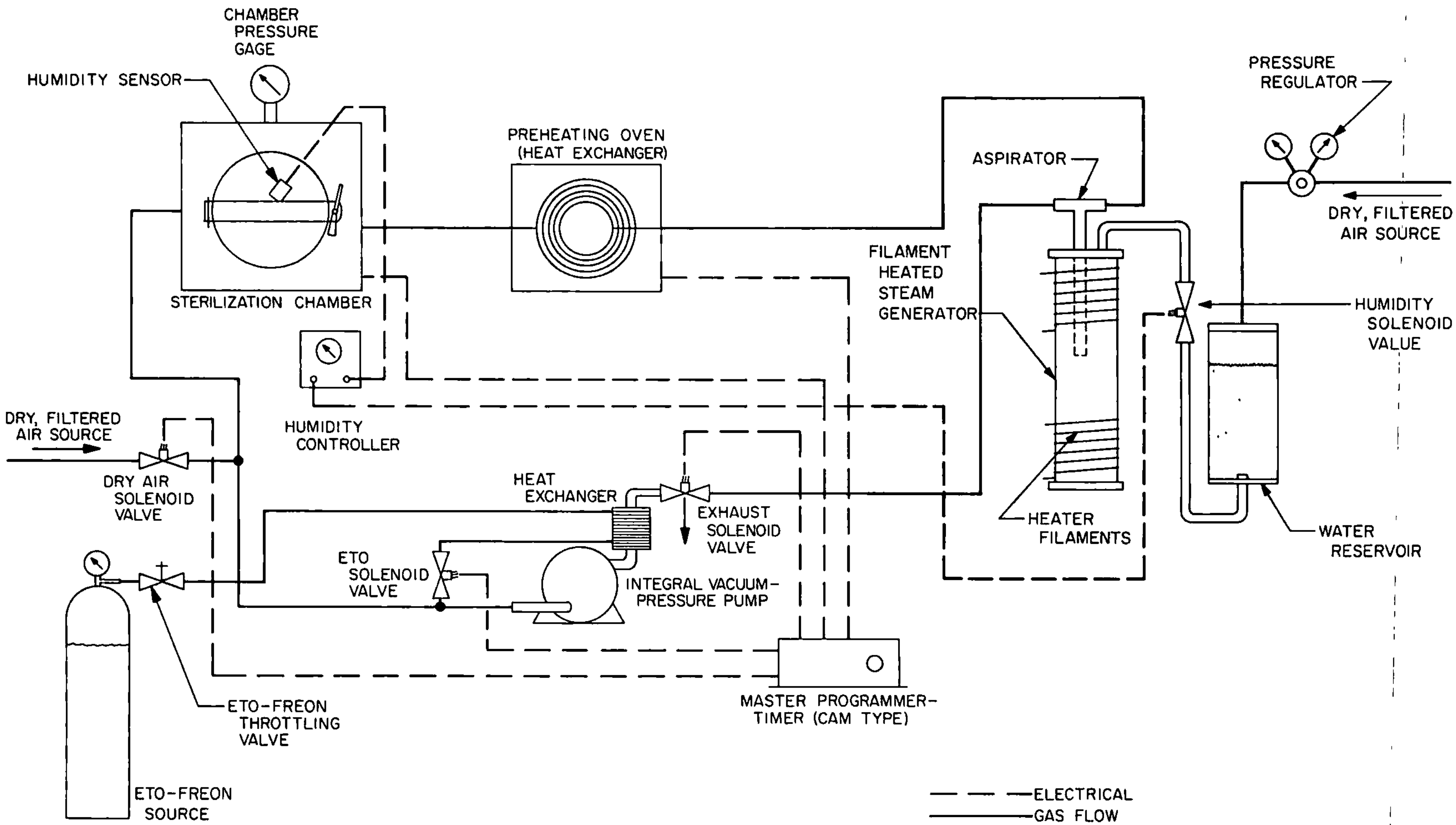

Fig. 2. Schematic of the automatic ETO–Freon 12 decontamination apparatus, showing modified steam injector

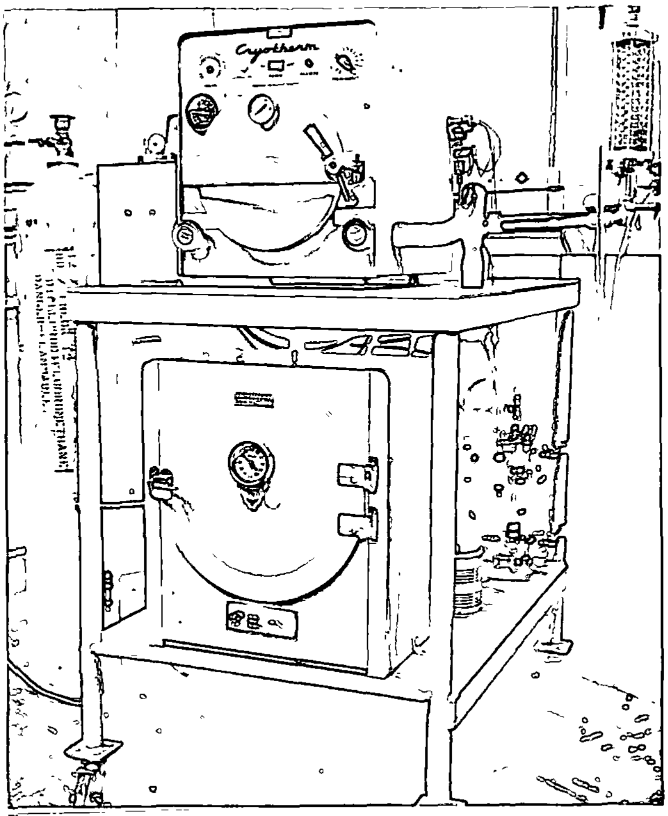

Fig. 3. The automatic ETO–Freon 12 decontamination setup

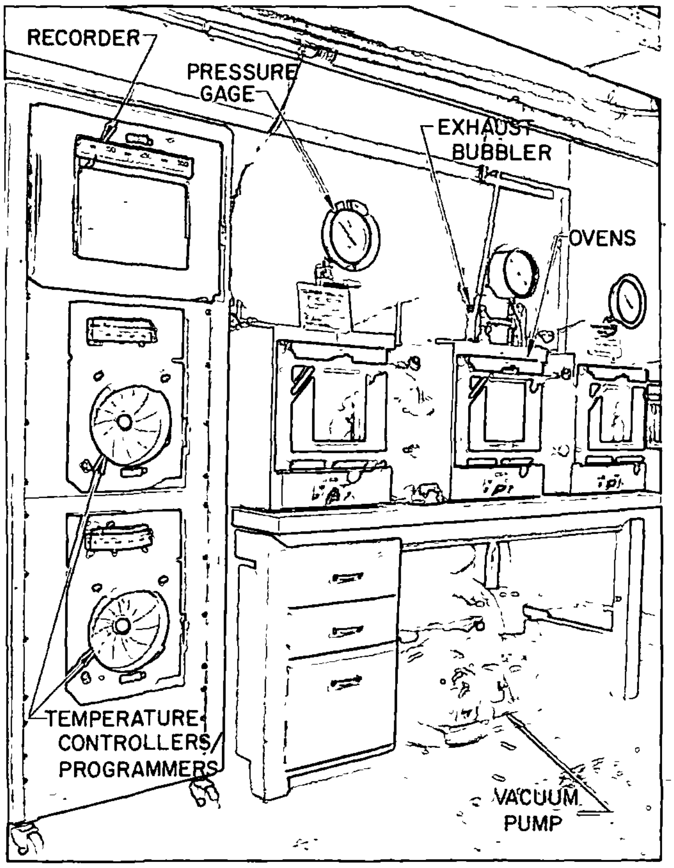

Fig. 4. The dry heat sterilization setup

2. ***Description of the dry heat sterilization apparatus.*** The apparatus employed in this phase of the study is illustrated in Fig 4. It is composed of the following complement of equipment. Three vacuum ovens[2] are used for the thermal cycling and a vacuum pump[3] is used to evacuate the ovens. This equipment is described more fully in Ref. 1. In addition, two process program controllers[4] with a calibrated accuracy of ½ of 1% full scale or ±1.4°C are connected through steel sheathed thermocouples to control the oven temperature. The temperature is read out in at least two locations within the ovens by means of similar steel sheathed thermocouples, the output of which is recorded on a potentiometer strip chart recorder.[5]

[2]Model 5850, National Appliance Company, Portland, Ore.

[3]Model 5KG, The New York Air Brake Co., Kinney Vacuum Div., 2323 Rosecrans, El Segundo, Calif.

[4]Barber-Colman Co., Industrial Instruments Div., Rockford, Ill.

[5]Series 8061, Barber-Colman Co.

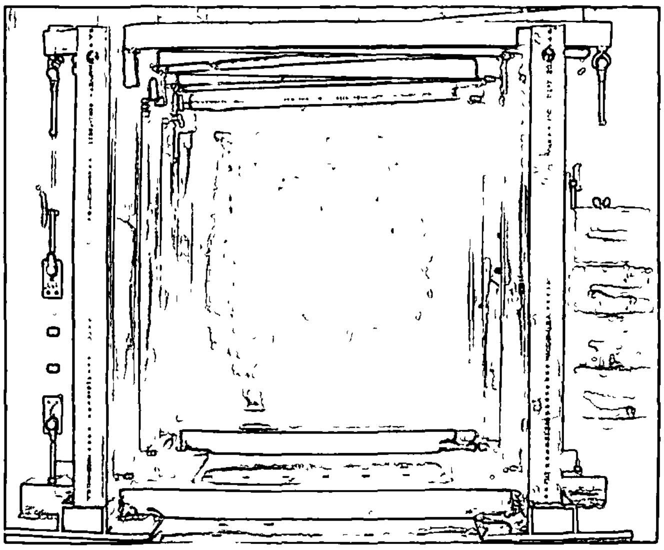

Fig. 5. The creep test apparatus

3. ***Description of the creep tester and procedure.*** The creep test apparatus employed in this study is based upon the ASTM specification D674-56 (Table 1). This lever-type loading apparatus, shown in Fig. 5, is placed

Table 1. Evaluation tests

Test	Adhesives	Coatings	Elastomers	Encapsulants	Films and Sheets	Foams	Plastics	Tapes	Wire Enamel	Standard
Hardness	X		X	X			X			ASTM D2240-64T, ASTM D785-62
Tensile strength			X	X	X	X	X			ASTM D412-62T and -64T, ASTM D882-64T, ASTM D1564-64T, ASTM D1623-64, ASTM D638-64T
Elongation			X	X	X	X	X	X		ASTM D412-62T and -64T, ASTM D882-64T, ASTM D1564-64T, ASTM D1623-64, ASTM D638-64T
Tear					X					ASTM D1004-61
Tensile shear strength	X									FTMS #175 — Method 1033.1T
Adhesion (peel, scrape)		X		X						ASTM D2197-63T, ASTM D1000-64
Breaking strength								X		ASTM D1000-64
Compression			X			X				ASTM D395-61 — Method B, ASTM D1564 — Suffix D
Flexibility		X								FTMS #141, Method 6223
Creep	X						X			ASTM D2294-64T (at 135°C), ASTM D674-56 (at 135°C)
Volume resistivity		X		X	X	X	X	X		ASTM D257-61T
Dielectric strength		X		X	X	X	X	X		ASTM D149-64
Volume change				X	X	X	X	X		Direct measurement using an Ames dial gage micrometer
Weight loss			X	X	X	X	X	X	X	Direct weight measurement using a Mettler Model H15 balance

in a large temperature-controlled oven. Prior to the testing, the lever arm ratios and dead weights are calibrated by means of an accurate spring scale. A 2-in. effective gage length is marked off on each specimen and measured accurately after applying the load but before elevating the temperature. After the exposure period, a total of 576 h at 135°C, the effective gage length is again accurately measured. During the entire exposure period the chamber is washed with a stream of dry nitrogen gas. The ends of each specimen are bonded to aluminum grips with epoxy adhesive and machine screws. The temperature during the entire test is accurately maintained within 1% by means of an automatic temperature controller and is recorded on a disc chart recorder by means of a thermocouple placed in the temperature chamber.

Table 2. Humidity and temperature control during an actual decontamination cycle

Cycle	Phase	Average % relative humidity	Average temperature, °F
1	Humidification	44	122
1	Pre-vacuum	n/a[a]	n/a
1	ETO–Freon 12 decontamination	44	122
1	Post-vacuum	n/a	n/a
1	Air-wash	45	123

[a]Values not applicable.

C. Decontamination and Dry Heat Sterilization Procedures

1. The ETO–Freon 12 decontamination procedure.

a. Cycles and phases. The operation of the decontamination apparatus described above is based upon JPL Specification VOL-50503-ETS. Each complete decontamination sequence consists of six identical cycles, each of which is, in turn, composed of five separate phases. These phases are, in order, (1) humidification in clean air for 2¾ h, (2) pre-vacuum at 60 torr for 18 min, (3) ETO–Freon 12 decontamination for 30 h at 600 ± 50 mg/liter ETO concentration at 50°C, (4) post-vacuum, also at 60 torr for 18 min, and, finally, (5) air-wash for 2¾ h. During each of the phases, except the vacuum phases, the temperature, pressure and humidity level is accurately controlled and the temperature recorded by means of four thermocouples and a strip-chart recorder. After completion of the sixth cycle, the apparatus is automatically shut off, or manually restarted, as required.

Table 2 shows actual values of temperature and humidity during a typical decontamination cycle. Tolerances are within the prescribed specification (Ref. 2).

b. Determination of ETO concentration. The concentration of ETO in the chamber mixture has been traditionally determined from the pressure in the chamber (Refs. 4 and 5). From Fig. 6 it can be shown that the concentration of ETO per unit volume is a direct function of the sterilizing gas pressure. This relationship depends upon, of course, the chamber gas temperature. However, it is also based upon perfect gas relationships and assumes no air leakage or other contamination. Since a perfectly leakproof apparatus is difficult to ensure over any extended period of time, a study was necessary to determine the actual ETO concentration as well as the concentration of other gases present in the chamber during actual operation.

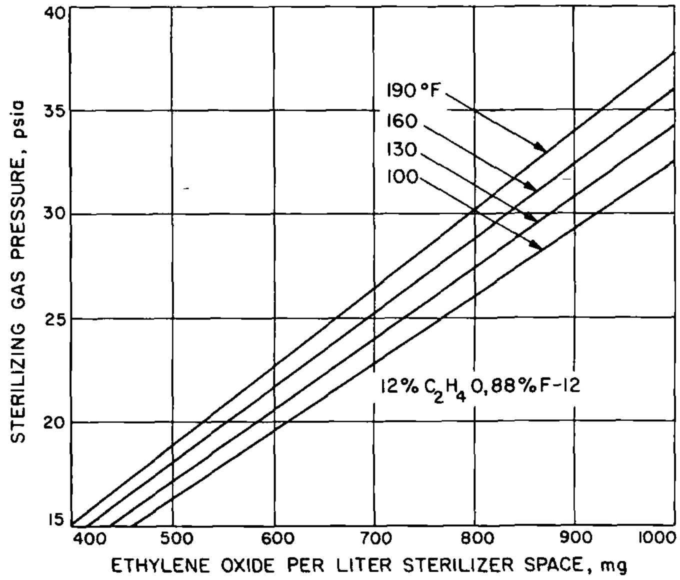

Fig. 6. Dependence of ETO concentration on temperature and pressure

The technique of gas chromatography was chosen because of its simplicity and reliability in both qualitative and quantitative analysis of gas mixtures (Ref. 6). A major problem was that of separating the four significant constituents known to be present in the decontamination chamber after circulation for some period of time. The constituents present are ETO, Freon 12, air and water vapor. After several trial runs with various chromatographic column packing materials and column temperatures, the recently developed Porapak (Ref. 7) material was selected. Types Q and R Porapak, which are composed of porous polymer beads modified by incorporating a polar monomer into the basic polymer structure, were chosen because of their ability to resolve all of the constituents present. Fig. 7 shows a chromatogram of the actual chamber gases. The results thus far of this chromatographic study may be summarized as follows:

The concentration of the component gases could be estimated by comparing the peak areas obtained for each with the peak areas obtained for known volumes (weights) of the individual components. Results of these analyses showed that the ETO concentration in the chamber was well within the tolerances specified (JPL Specification VOL-50503-ETS). Values for the ETO concentration obtained from pressure readings and gas chromatographic analysis were not in full agreement. To achieve full confidence in the accuracy of the gas chromatographic method, sampling and other techniques are under study for improvement.

c. Determination of relative humidity. Accurate humidity levels are maintained during each of the phases by means of a commercially available humidity indicator–controller. The humidity sensor, which is placed directly in the decontamination chamber, is a copolymer of styrene, sulfonated at the surface to make it sensitive to humidity. The electrodes are silver paint. Employing the principle of *adsorption*, rather than *absorption*, the sensing element experiences very rapid uptake or release of water vapor with slight variation in relative humidity. The corresponding rapid changes in relative humidity of the sensor result in a logarithmic change in electrical resistance which is displayed by a meter on the controller instrument (Refs. 8 and 9).

The sensor and controller are recalibrated before and after each sequence by means of a precision resistor which, when substituted in the circuit for the sensor, will cause the indicator dial to read 100% relative humidity if proper calibration has been maintained. The sensor is also checked against a calibrated Foxboro hair-type, temperature-corrected, humidity recorder. Experience to this date indicates that the sensor can sustain several repeated sequences in ETO–Freon 12 environments at elevated temperature without significant loss of

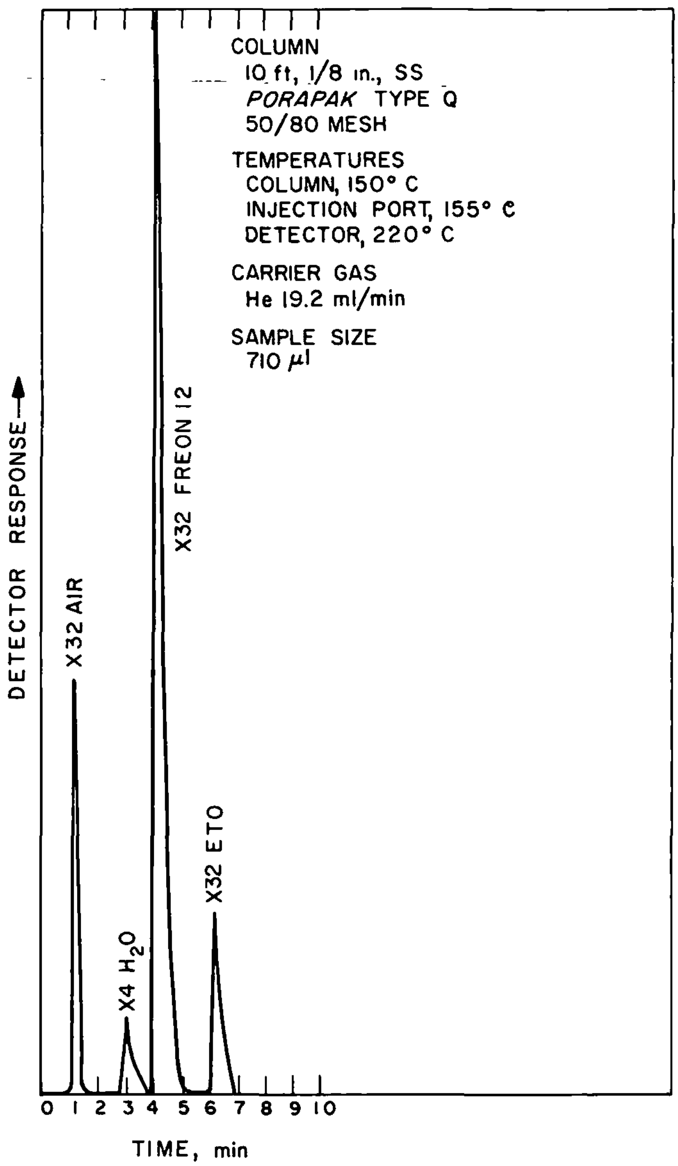

Fig. 7. Chromatogram of the ETO decontamination chamber gases

sensitivity. Further study in this area is being carried out at the present time.

2. *The dry heat sterilization procedure.* The samples were placed in vacuum ovens on metal racks, along with three steel-sheathed thermocouples. The oven doors were clamped, and the ovens evacuated to 28.5 in. of mercury with a vacuum pump. The ovens were then purged with dry nitrogen of high purity; evacuation and purging were repeated two more times, ending with a nitrogen purge. Nitrogen was kept flowing through the ovens during each entire cycle at a rate of approximately 10 ml/min.

The program temperature controllers were then turned on and set for the programmed sequence, as required by the JPL specification, which is composed of a uniform temperature rise of 56.5°C per h to 135°C, then held constant for 92 h and finally returned to room temperature (22°C) at the same temperature rate as used for the temperature rise. The performance of the vacuum ovens was evaluated by mass spectrographic analysis of the oven atmosphere. The gases were analyzed at the beginning and the end of a cycle, with and without samples in the ovens. The following results are typical:

Beginning of cycle, no samples:	0.01 mole % oxygen
End of cycle (96 h), no samples:	0.02 mole % oxygen 0.01 mole % carbon dioxide
Beginning of cycle, with samples:	0.01 mole % oxygen
End of cycle (96 h), with samples:	0.03 mole % oxygen 0.01 mole % carbon dioxide

D. Tests Used

Tests were performed in full compliance with the applicable standard test methods. For each class of products the tests and the methods used during the entire program are given in Table 2. Weight losses were measured to an accuracy of ±0.1 mg and volume change measurements were accurate to ±0.1 mil.

IV. Discussion

A. Criteria and Rating

Certain criteria are necessary for rating the compatibility of a product with the sterilization environments. The bases for the criteria used in this report were discussed previously (Ref. 1).

The criteria used vary from one class to another; however, those used for electrical properties, mechanical properties (hardness excepted) and weight loss are common to all and are given here. Those that are specific to individual classes are presented separately in the discussion of each class.

1. Electrical properties. Threshold values were set for electrical values as follows:

volume resistivity, 10^7 Ω-cm

dielectric strength, 200 V/mil

Products were considered *compatible* where the two electrical measurements remained greater than the threshold values, the decrease in volume resistivity was less than 10^3 Ω-cm and the loss in dielectric strength was no more than 25% of the original value. They were rated *not compatible* where any one of these criteria was not met. Products with borderline values were rated *marginal.* The dielectric strength of some products (for example, the polyurethane foams) was below 200 V/mil both before and after the test. Such cases were considered *compatible* because the original property or the quality of the product was not being assessed.

2. Mechanical properties and weight loss. The following criteria for mechanical properties and weight loss were applied to the products after dry heat sterilization:

(1) Compatible (C): The product retained 80% or more of its original mechanical properties; weight loss was less than 1%.

(2) Marginal (M): The product retained 70 to 80% of its original mechanical properties; weight loss was between 1 and 4%.

(3) Not Compatible (NC): The product retained less than 70% of its original properties; weight loss was more than 4%.

B. Results and Discussion of Materials Exposed to ETO–Freon 12 and Dry Heat at 135°C

In the discussion of results that follows, reference should be made to the schedule of applicable tests, Table 2.

1. Adhesives. A summary of ETO–Freon 12 exposure and dry heat exposure test results for adhesives is given in Tables 3 and 4, respectively. (Detailed data are found in Table A-1.)

After the ETO–Freon 12 exposure, the adhesives showed softening, a decrease in lap shear strength and an increase in weight. Two nonstructural adhesives, numbers 4 and 5 in Table 3, showed weight losses. Being solvent-based adhesives, complete evaporation of solvent had not taken place during the cure period recommended by the manufacturer. It was a requirement for this study to follow the manufacturer's recommendations for handling materials. The weight gains and other changes in properties are ascribed to either the absorption of the sterilant gas mixture, or even a reaction with ETO.

Table 3. Summary of test results for ETO decontamination procedure[a] on ADHESIVES

No.	Commercial designation	Material, type	Manufacturer	Mechanical properties				Thermal property
				Hardness, Shore		Shear strength, psi		Weight change, %
				Control	Test	Control	Test	
1	EC 1614 B/A	Epoxy/polyamide	3M Company	69.7 D	69.3 D	1420	1270	+2.691
2	EC 2216 B/A	Epoxy/amine	3M Company	52.9 D	43.1 D	1030	720	+2.251
3	Eccobond 45/15	Epoxy/amine	Emerson and Cuming	60.1 D	36.9 D	1303	800	+9.533
4	4684/RC-805	Synthetic rubber	Du Pont	41.7 A	40.7 A	145	130	−2.805
5	46950	Polyester	Du Pont	—	—	100	110	−6.102
6	RTV-40/T-12	Silicone	General Electric	34.1 A	30.3 A	167	133	+0.389

[a]Six cycles of 28 h each at 50°C and 50 ±5% relative humidity.

Table 4. Summary of test results for ETO decontamination[a] and dry heat sterilization[b] procedure on ADHESIVES

No.	Commercial designation	Mechanical properties					Thermal property	Compatibility rating
		Hardness, Shore		Shear strength, psi		Creep[c]	Weight change, %	
		Control	Test	Control	Test			
1	EC-1614 B/A	69.7 D	68.7 D	1420	1730	Failed	+0.256	NC
2	EC-2216 B/A	52.9 D	51.0 D	1030	2040	Failed	+0.221	NC
3	Eccobond 45/15	60.1 D	44.3 D	1303	2080	Failed	>+0.5	NC
4	4684/RC 805	41.7 A	—	145	156		−10.513	NC
5	46950	—	—	100	> 138		−9.227	NC
6	RTV-40/T-12	34.1 A	40.1 A	167	310		−0.661	C

[a]Six cycles of 28 h each at 50°C and 50 ±5% relative humidity.
[b]Six cycles of 92 h each at 135°C in dry nitrogen.
[c]Carried out at 135°C.

After the dry heat exposure, the specimens regained hardness. Lap shear strengths increased above the original values and there was, generally, a net loss of weight. The weight gains reported for EC-1614 and EC-2216 in Table 4 are an indication that ETO had probably reacted with the active hydrogen-containing groups, such as -OH and -NH of the amine-cured epoxy resins.

The first three products of Table 4 were tested as structural adhesives. Creep tests at 135°C were assigned to them. The constant load applied to the test specimens was approximately 40% of the tensile shear strength measured at 135°C. Eccobond 45/15 melted at 135°C and testing for creep was considered unnecessary. The other two failed the test during the first hours of the required testing period of 550 h. On the basis of the creep test, these three adhesives were rated NC. The non-structural adhesives, 4684 and 46950 were rated NC because of high weight loss. Only RTV-40 could be rated C.

2. Coatings. A summary of test results after ETO–Freon 12 exposure and dry heat exposure are given in Tables 5 and 6, respectively. (Detailed data are found in Table A-2.)

The four products evaluated were primers rather than protective coatings. Tests normally assigned to coatings were used for their evaluation. They were rated

(1) C, if, after dry heat sterilization,

(a) Scrape adhesion was more than 1.5 kg.

(b) Flexibility test was passed.

(c) No surface changes (blisters or pinholes) appeared.

(d) Electrical criteria were met.

(2) M, where either

(a) Scrape adhesion was 0.5 to 1.5 kg.

(b) Electrical properties were borderline.

(3) NC, where either

(a) Scrape adhesion was less than 0.5 kg.

(b) Flexibility test was not passed.

(c) Surface condition requirements were not met.

(d) Any one of the electrical criteria were not met.

Weight loss measurements were not made on these primers, because they were all solvent-based, and complete evaporation of solvent could not be effected during the recommended cure period.

Chemlock 607 crumbled after ETO–Freon 12 exposure. Primers SS-4101 and SS-4044 failed the flexibility test after dry heat exposure. Only one primer, SS-4004, could be rated C.

The volume resistivities and dielectric strengths of coatings before and after exposure to ETO and dry heat sterilization are shown graphically in Figs. 8 and 9, respectively.

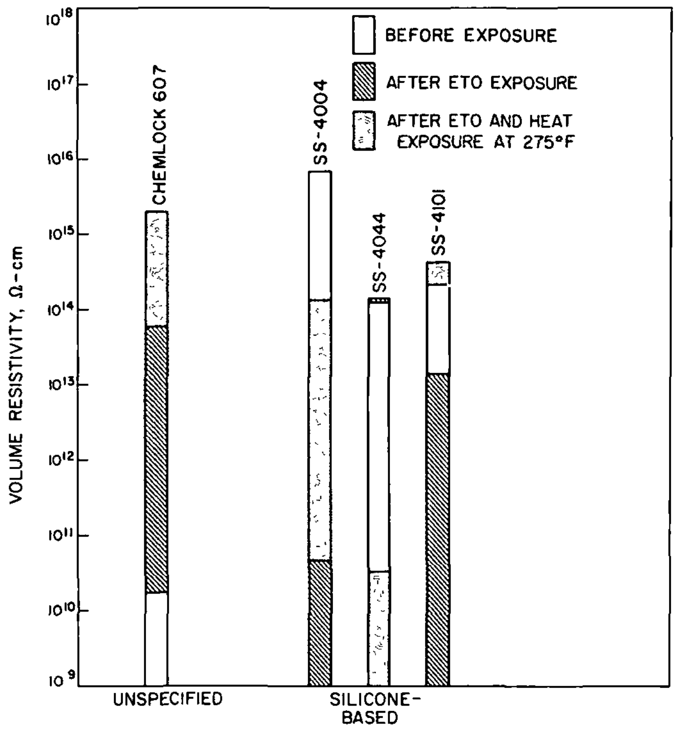

Fig. 8. Volume resistivities of Coatings at room temperature, before and after exposure to sterilization conditions

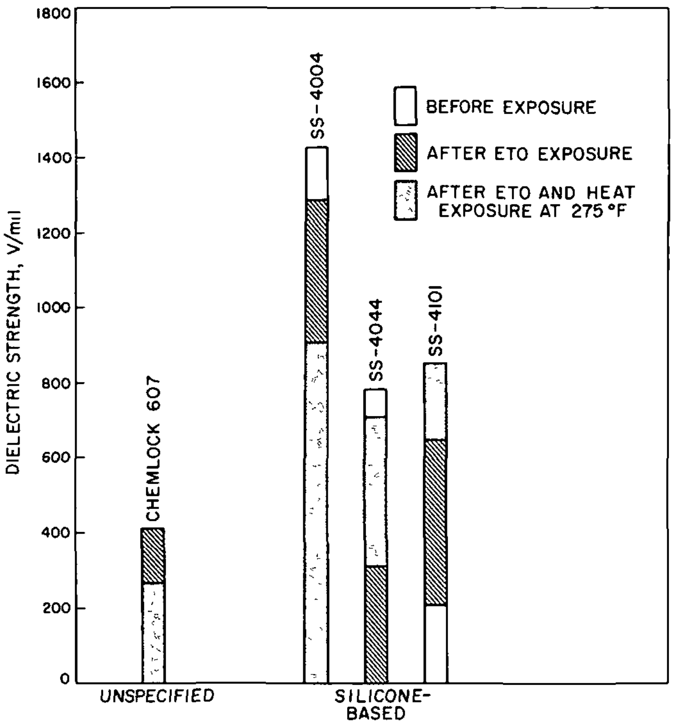

Fig. 9. Dielectric strength of Coatings at room temperature, before and after exposure to sterilization conditions

Table 5. Summary of test results for ETO decontamination procedure[a] on COATINGS

No.	Commercial designation	Material, type	Manufacturer	Mechanical properties: Scrape adhesion, kg		Mechanical properties: Flexibility		Electrical properties: Volume resistivity, Ω–cm		Electrical properties: Dielectric strength, V/mil	
				Control	Test	Control	Test	Control	Test	Control	Test
1	Chemlock 607		Hughson Chemical	1.1	Failed	Failed	Failed	2.5×10^{10}	7.89×10^{13}	—	265
2	SS-4004	Silicone	General Electric	0.5	1.7	Failed	Passed	8.3×10^{15}	6.7×10^{10}	909	1291
3	SS-4101	Silicone	General Electric	1.0	0.5	Passed	Passed	3.3×10^{14}	1.5×10^{13}	207	643
4	SS-4044	Silicone	General Electric	0.5	0.5	Failed	Failed	1.04×10^{14}	1.65×10^{14}	782	309

[a]Six cycles of 28 h each at 50°C and 50 ±5% relative humidity.

Table 6. Summary of test results for ETO decontamination[a] and dry heat sterilization[b] procedure on COATINGS

No.	Commercial designation	Mechanical properties: Scrape adhesion, kg		Mechanical properties: Flexibility		Electrical properties: Volume resistivity, Ω–cm		Electrical properties: Dielectric strength, V/mil		Compatibility rating
		Control	Test	Control	Test	Control	Test	Control	Test	
1	Chemlock 607	1.1	Failed	Failed	Failed	2.5×10^{10}	3.0×10^{15}	—	412	NC
2	SS-4004	0.5	2.2	Failed	Passed	8.3×10^{15}	1.17×10^{14}	909	1430	C
3	SS-4101	1.0	1.8	Passed	Failed	3.3×10^{14}	6.4×10^{14}	207	855	NC
4	SS-4044	0.5	3.5	Failed	Failed	—	—	—	—	NC

[a]Six cycles of 28 h each at 50°C and 50 ±5% relative humidity.
[b]Six cycles of 92 h each at 135°C in dry nitrogen.

Table 7. Summary of test results for ETO decontamination procedure[a] on ELASTOMERS

No.	Commercial designation	Material type	Manufacturer	Mechanical properties						Physical and thermal properties	
				Hardness, Shore A		Tensile strength, psi		Elongation, %		Volume change, %	Weight change, %
				Control	Test	Control	Test	Control	Test		
1	Butyl 318-7	Butyl	Parker Seal Co.	72.5	67.1	1620 (bars) 1710 (rings)	1600 (bars) 1500 (rings)	300 (bars) 275 (rings)	317 (bars) 333 (rings)	+0.150	+0.927

[a]Six cycles of 28 h each at 50°C and 50 ±5% relative humidity.

Table 8. Summary of test results for ETO decontamination[a] and dry heat sterilization[b] procedure on ELASTOMERS

No.	Commercial designation	Mechanical properties							Physical and thermal properties		Compatibility rating
		Hardness, Shore A		Tensile strength, psi		Elongation, %		Compression set, %	Volume change, %	Weight change, %	
		Control	Test	Control	Test	Control	Test	Test[c]			
1	Butyl 318-7	72.5	68.2	1620 (bars) 1710 (rings)	1530 (bars) 1540 (rings)	300 (bars) 275 (rings)	317 (bars) 295 (rings)	74.8	−0.593	−1.969	M

[a]Six cycles of 28 h each at 50°C and 50 ±5% relative humidity.

[b]Six cycles of 92 h each at 135°C in dry nitrogen.

[c]After 552 h at 135°C in dry nitrogen.

Table 9. Summary of test results for ETO decontamination procedure[a] on ENCAPSULANTS

No.	Commercial designation	Material type	Manufacturer	Mechanical properties						Electrical properties				Physical and thermal properties	
				Hardness, Shore A		Tensile strength, psi		Elongation, %		Volume resistivity, Ω—cm		Dielectric strength, V/mil		Volume change, %	Weight change, %
				Control	Test	Control	Test	Control	Test	Control	Test	Control	Test		
1	PR-1527 A/B	Polyurethane	Products Research	78.5	77.9	1970	1700	550	570	1.28×10^{12}	3.77×10^{11}	437	441	+0.772	+0.649
2	PR-1535	Polyurethane	Products Research	88	88	1710	1820	545	450	5.7×10^{11}	5.4×10^{13}	434	>341	+1.067	+1.36
3	PR-1538	Polyurethane	Products Research	77	74.2	1027	950	565	707	2.4×10^{13}	1.0×10^{13}	>462	>390	+0.558	+1.72
4	PR-1547	Polyurethane	Products Research	81	71	1905	1167	520	663	3.3×10^{12}	2.3×10^{13}	>456	>356	+3.888	+1.57
5	RTV-30/T-12	Silicone	General Electric	55	54.9	586	476	90	97	4.17×10^{14}	2.37×10^{14}	486	>490	−0.346	+0.331
6	RTV-3116 (formerly RTV-881)	Silicone	Dow Corning	32.4	31.5	204	250	157	140	5.36×10^{12}	7.83×10^{11}	417	443	+3.571	−0.824
7	Solithane 1/T-12	Polyurethane	Thiokol Chemical	58.9	60.5	413	408	90	93	9.9×10^{14}	1.32×10^{14}	>478	431	−0.249	+2.538
8	Solithane 4/T-12	Polyurethane	Thiokol Chemical	56.2	56.2	230	240	67	77	8.75×10^{13}	1.68×10^{13}	456	>481	+1.140	+2.469
9	Solithane 12/T-12	Polyurethane	Thiokol Chemical	68	70.3	2030	1930	137	140	1.49×10^{15}	8.79×10^{14}	472	>481	+1.127	+1.114

[a]Six cycles of 28 h each at 50°C and 50 ±5% relative humidity.

Table 10. Summary of test results for ETO decontamination[a] and dry heat sterilization[b] on ENCAPSULANTS

No.	Commercial designation	Mechanical properties						Electrical properties				Physical and thermal properties		Compatibility rating
		Hardness, Shore A		Tensile strength, psi		Elongation, %		Volume resistivity, Ω—cm		Dielectric strength, V/mil		Volume change, %	Weight change, %	
		Control	Test	Control	Test	Control	Test	Control	Test	Control	Test			
1	PR-1527 A/B	78.5	61	1970	Failed[c]	550	Failed[c]	1.28×10^{12}	1.07×10^{12}	437	442	−0.200	−1.306	NC
2	PR-1535	88	84.1	1710	>2820	545	>600	5.70×10^{11}	4.50×10^{12}	434	441	+0.583	−0.356	C
3	PR-1538	77	74	1027	857	565	842	2.4×10^{13}	7.0×10^{12}	>462	>427	+0.208	−0.470	C
4	PR-1547	81	75.6	1905	899	520	783	3.3×10^{13}	9.7×10^{13}	>456	>357	+2.439	−0.732	NC
5	RTV-30/T-12	55	57.8	536	530	90	110	3.17×10^{14}	7.32×10^{14}	486	491	−0.561	−0.339	C
6	RTV-3116 (formerly RTV-881)	32.4	44.2	204	161	157	105	5.36×10^{12}	2.69×10^{12}	450	478	+5.532	−3.167	M
7	Solithane 1/T-12	58.9	45.8	413	246	90	130	9.9×10^{14}	2.54×10^{13}	>478	471	−0.731	+0.825	NC
8	Solithane 4/T-12	56.2	42.4	230	170	67	145	8.75×10^{13}	1.02×10^{13}	456	409	−0.300	+0.899	M
9	Solithane 12/T-12	68	68	2030	1540	137	145	1.49×10^{15}	1.24×10^{15}	472	471	−0.050	−1.249	M

[a]Six cycles of 28 h each at 50°C and 50 ±5% relative humidity.
[b]Six cycles of 92 h each at 135°C in dry nitrogen.
[c]Crumbles.

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3. Elastomers. One elastomeric product only, Butyl 318-7, was evaluated during the report period. Summary of test results is given in Tables 7 and 8. (Detailed data are found in Table A-3.)

The Butyl rubber product softened somewhat (5 units) and showed an increase in volume after ETO–Freon 12 exposure, presumably because of absorption of the sterilant gas mixture. The other mechanical properties tested were not affected significantly.

The compression set of the product was determined after exposure to 135°C for 550 hours. The 75% set encountered was not unexpected, considering the severity of the test. The product was rated M, on the basis of weight loss and % compression set.

No electrical measurements were made on Butyl 318-7, because it is not used as an insulator.

4. Encapsulants. Tables 9 and 10 summarize the test results for the ETO–Freon 12 exposure and dry heat exposure, respectively, for the encapsulants. Detailed results are provided in Table A-4 of Appendix A.

The term *encapsulant* as used here includes such compounds as those used for potting, embedment, conformal coating or sealing. It also means a liquid, castable material that can be poured into a mold, pot, or cavity, or applied to a surface and cured in place to the solid state.

The following criteria for hardness and volume change were used in addition to those listed on page 10 to rate the encapsulants after dry heat exposure:

(1) C, where drop in hardness was less than 10 units, and volume change less than 4%.

(2) M, where drop in hardness was more than 10 but less than 15 units, and volume change was 4 to 6%.

(3) NC, where drop in hardness was more than 15 units, and volume change was more than 6%.

In addition to the tests shown in Tables 9 and 10, the peel strengths of all the encapsulants were also measured but not used for rating. (They are reported in Table A-4.) All polyurethane encapsulants were applied to bare aluminum and, thus, low peel strengths were obtained before and after exposure. An exception was the solithane formulation 12, which had triisopropanolamine as part of its curing agent. It showed a peel strength of 25 lb/in. after dry heat sterilization. Unfortunately, this formulation had difficult handling problems (Appendix C). The RTV-30 was applied on aluminum primed with SS-4004 and showed 3 lb/in. peel strength after dry heat sterilization. The RTV-3116, which was applied without primer, showed very little peel strength.

In practically all cases, a weight gain accompanied by volume increase was experienced by the encapsulants after ETO–Freon 12 exposure. The weight loss suffered by RTV-3116, Table 9, is attributed to more volatile material lost at 50°C, the temperature condition in the ETO decontamination chamber, than gain of material by absorption of sterilant gas. The mechanical properties of the encapsulants were not seriously affected by ETO–Freon 12 exposure.

Changes in the properties of encapsulants after both ETO–Freon 12 and dry heat exposures are given in Table 11.

Dry heat exposure had distinct effects on the mechanical properties of the encapsulants. Seriously affected was PR-1527, which failed badly the tensile test under small load. Less affected was PR-1547, but still enough change had occurred to rate it NC. The tensile strength of PR-1535 increased after dry heat exposure and that of PR-1538 remained above 80% of its original value. They were the only polyurethane encapsulants rated C. The solithane formulation 1 was rated NC because of 40% loss in tensile strength. Solithanes 4 and 12 were rated M for tensile losses of about 25%. The latter also showed a weight loss of more than 1%. RTV-3116 was rated M because of volume change and weight loss. RTV-30 met the criteria for compatibility and was rated C.

A flexible polyurethane foam, Eccofoam FS, and a rigid one, Eccofoam SH (Tables 12 and 13) were also evaluated. Since they are used oftentimes as encapsulants, they are discussed here.

The flexible foam suffered significant loss in tensile strength after ETO–Freon 12 exposure. The increase in weight and volume indicated the absorption of and swelling in the sterilant gas mixture. The rigid foam was not so affected. Both passed the compression load deflection test. The flexible foam was rated NC because of loss in weight and mechanical properties after dry heat sterilization. The rigid foam showed close to 2% loss in weight and, as a consequence of this, was rated M.

Table 11. Changes in mechanical properties of ENCAPSULANTS after ETO decontamination and dry heat sterilization

Material type and product	After ETO exposure			After ETO and dry heat exposure at 135°C		
	Unit change in hardness	Tensile strength, % retained	Elongation, % retained	Unit change in hardness	Tensile strength, % retained	Elongation, % retained
Polyurethane						
Eccofoam FS		69	90		60	58
Eccofoam SH		103	79		106	82
PR-1527	−0.6	86	104	−17.5	Failed	Failed
PR-1535	0	106	83	−4	165	110
PR-1538	−3.1	93	125	−3	83	149
PR-1547	−10	61	128	−5.4	47	151
Solithane 1/T-12	+1.4	99	103	−13.1	60	144
Solithane 4/T-12	0	104	115	−13.8	74	216
Solithane 12/T-12	+2.3	95	102	0	76	106
Silicone						
RTV-30	0	90	122	+2.8	95	108
RT-3116	−1	123	89	+11.8	79	67

The changes in the electrical properties of the encapsulants are pictured graphically in Figs. 10 and 11. None failed the criteria set for electrical properties, although some significant changes occurred.

*5. **Films.*** Summaries of test results for films after ETO–Freon 12 and dry heat exposures are given in Tables 14 and 15, respectively. Changes in properties are shown in Table 16. (Detailed data are found in Table A-5.)

The ETO–Freon 12 exposure had little effect on the tear and tensile properties of the films tested. They suffered losses in elongation, however, particularly Mylar T and Tedlar 100 BG. As with the Eccofoam FS, there was a normal weight gain on exposure to sterilant gas mixture. Mylar T and Fibremat I 2539, however, kept the gained weight after dry heat exposure, once more suggesting a possible reaction of ETO with these two polyesters. Kapton 100, showing satisfactory resistance to both ETO–Freon 12 and dry heat exposures, was rated C. The other three were rated NC because after exposure to dry heat they suffered losses in one or more mechanical properties.

The changes in the electrical properties of films are given in Figs. 12 and 13. The low dielectric strength of Fibremat I 2539 is due to its porous texture. No significant changes in electrical properties occurred after exposure to the sterilization conditions.

*6. **Plastics.*** Summaries of test results after ETO–Freon 12 and dry heat exposures for plastics are presented in Tables 17 and 18, respectively. (Detailed data are provided in Table A-6.)

The ETO–Freon 12 exposure affected considerably the tensile and elongation properties of Delrin 507 and Zytel 38. About 40% only of the original tensile strength was retained. The losses were not regained after exposure to dry heat (Table 19). Moreover, the failure of these materials in the creep test performed at 135°C showed a high degree of permanent set. Both the epoxy/glass laminate, EG-899, and the phenolic/glass laminate, Fiberglas 91 LD, showed excellent performance mechanically. The latter, however, showed a weight loss of more than 1% after the dry heat exposure and had to be rated M.

The electrical properties were not affected significantly either after ETO–Freon 12 exposure or after dry heat exposure (Figs. 14, 15).

Table 12. Summary of test results for ETO decontamination procedure[a] on FOAMS

No.	Commercial designation	Material type	Manufacturer	Mechanical properties: Tensile strength, psi		Elongation, %		Compression load deflection test, 25% psia		Electrical properties: Volume resistivity, Ω—cm		Dielectric strength, V/mil		Physical and thermal properties: Volume change, %	Weight change, %
				Control	Test	Control	Test	Control	Test	Control	Test	Control	Test		
1	Eccofoam FS	Polyurethane (flexible)	Emerson and Cuming	50.2	34.6	331	299	0.74	0.82	4.1×10^{11}	2.3×10^{11}	32.7	27.7	+5.026	+3.310
2	Eccofoam SH	Polyurethane (rigid)	Emerson and Cuming	127	131	76	60	169	155	3.9×10^{15}	2.7×10^{15}	40.0	45.3	+0.420	+0.333

[a]Six cycles of 28 h each at 50°C and 50 ±5% relative humidity.

Table 13. Summary of test results for ETO decontamination[a] and dry heat sterilization[b] procedure on FOAMS

No.	Commercial designation	Mechanical properties: Tensile strength, psi		Elongation, %		Compression load deflection test, 25% psia		Electrical properties: Volume resistivity, Ω—cm		Dielectric strength, V/mil		Physical and thermal properties: Volume change, %	Weight change, %	Compatibility rating
		Control	Test	Control	Test	Control	Test	Control	Test	Control	Test			
1	Eccofoam FS	50.2	30	331	193	0.74	1.4	4.1×10^{11}	1.13×10^{13}	34.5	32.2	−1.118	−4.606	NC
2	Eccofoam SH	127	135	76	62	169	174	3.9×10^{15}	2.7×10^{15}	40.0	48.7	−1.545	−1.783	M

[a]Six cycles of 28 h each at 50°C and 50 ±5% relative humidity.

[b]Six cycles of 92 h each at 135°C in dry nitrogen.

Table 14. Summary of test results for ETO decontamination procedure[a] on FILMS

No.	Commercial designation	Material type	Manufacturer	Mechanical properties: Tensile strength, psi		Mechanical properties: Elongation, %		Mechanical properties: Tear strength, lb/mil		Electrical properties: Volume resistivity, Ω—cm		Electrical properties: Dielectric strength, V/mil		Physical and thermal properties: Volume change, %	Physical and thermal properties: Weight change, %
				Control	Test	Control	Test	Control	Test	Control	Test	Control	Test		
1	Kapton 100-XH-667	Polyimide	Du Pont	13,700	11,500	6.8	7.8	0.56	0.58	7.5×10^{16}	6.4×10^{16}	4930	5540	−0.222	+0.959
2	Mylar Type T	Polyester	Du Pont	10,500	10,850	10.7	6.5	1.30	1.08	8.6×10^{16}	8.9×10^{15}	3960	4070	0	+2.091
3	Tedlar 100 BG 30 WH	Poly(vinyl fluoride)	Du Pont	10,925	10,500	47.4	35.4	1.22	0.99	2.4×10^{15}	3.0×10^{16}	3280	3310	−0.158	−0.56
4	Fibremat I 2539	Polyester, unreinforced	3M Co.	2,230	2,203	111	87	0.72	0.73	3.6×10^{15}	3.0×10^{16}	76	61	0	+4.967

[a]Six cycles of 28 h each at 50°C and 50 ±5% relative humidity.

Table 15. Summary of test results for ETO decontamination[a] and dry heat sterilization[b] procedure on FILMS

No.	Commercial designation	Mechanical properties: Tensile strength, psi		Mechanical properties: Elongation, %		Mechanical properties: Tear strength, lb/mil		Electrical properties: Volume resistivity, Ω—cm		Electrical properties: Dielectric strength, V/mil		Physical and thermal properties: Volume change, %	Physical and thermal properties: Weight change, %	Compatibility rating
		Control	Test	Control	Test	Control	Test	Control	Test	Control	Test			
1	Kapton 100-XH-667	13,700	12,700	6.8	8.3	0.56	0.54	7.5×10^{16}	1.2×10^{17}	4930	5350	−0.398	−0.200	C
2	Mylar Type T	10,500	14,200	10.7	6.3	1.30	1.45	8.6×10^{16}	3.0×10^{16}	3960	3850	Wrinkles[c]	+0.318	C
3	Tedlar 100 BG 30 WH	10,925	7,400	47.4	26.2	1.22	1.16	2.4×10^{15}	5.3×10^{14}	3280	3340	−4.570	−0.040	M
4	Fibremat I 2539	2,230	2,660	111	50	0.72	0.62	3.6×10^{15}	2.9×10^{16}	76	76	−1.501	+0.144	NC

[a]Six cycles of 28 h each at 50°C and 50 ±5% relative humidity.

[b]Six cycles of 92 h each at 135°C in dry nitrogen.

[c]Sample curls and wrinkles.

Table 16. Changes in mechanical properties of FILMS *after* ETO decontamination and dry heat sterilization

Product and material type	After ETO exposure			After ETO and dry heat exposure at 135°C		
	Tensile strength, % retained	Elongation, % retained	Tear strength, % retained	Tensile strength, % retained	Elongation, % retained	Tear strength, % retained
Mylar Type T (polyester)	103	60	83	135	59	112
Fibremat I 2539 (polyester)	99	78	101	119	45	86
Kapton 100-XH-667 (polyimide)	84	115	104	92	122	96
Tedlar 100 BG 30 WH poly(vinyl fluoride)	96	75	81	68	55	95

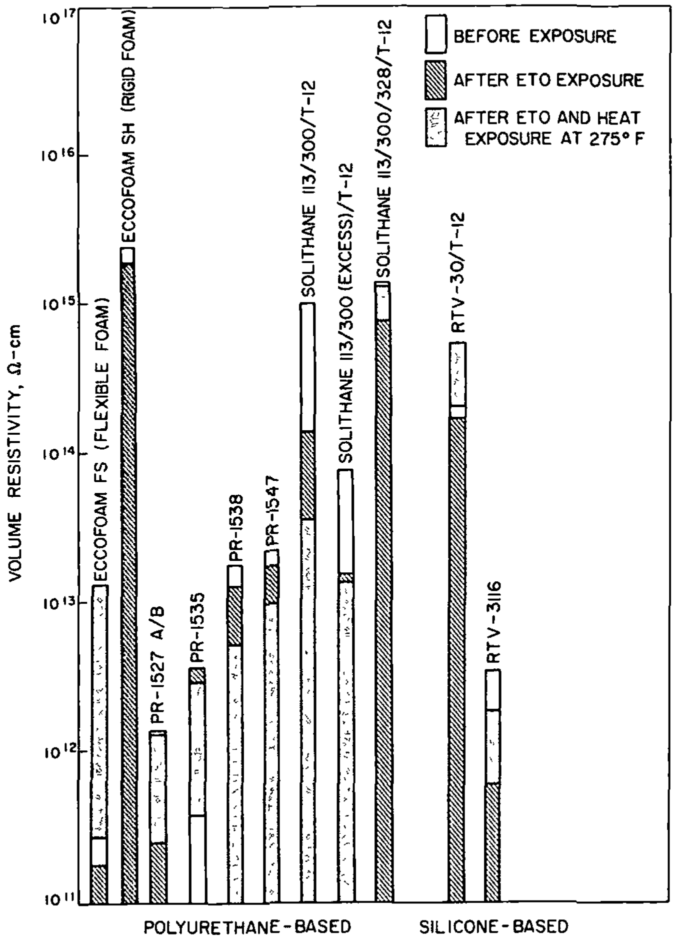

Fig. 10. Volume resistivities of Encapsulants at room temperature, before and after exposure to sterilization conditions

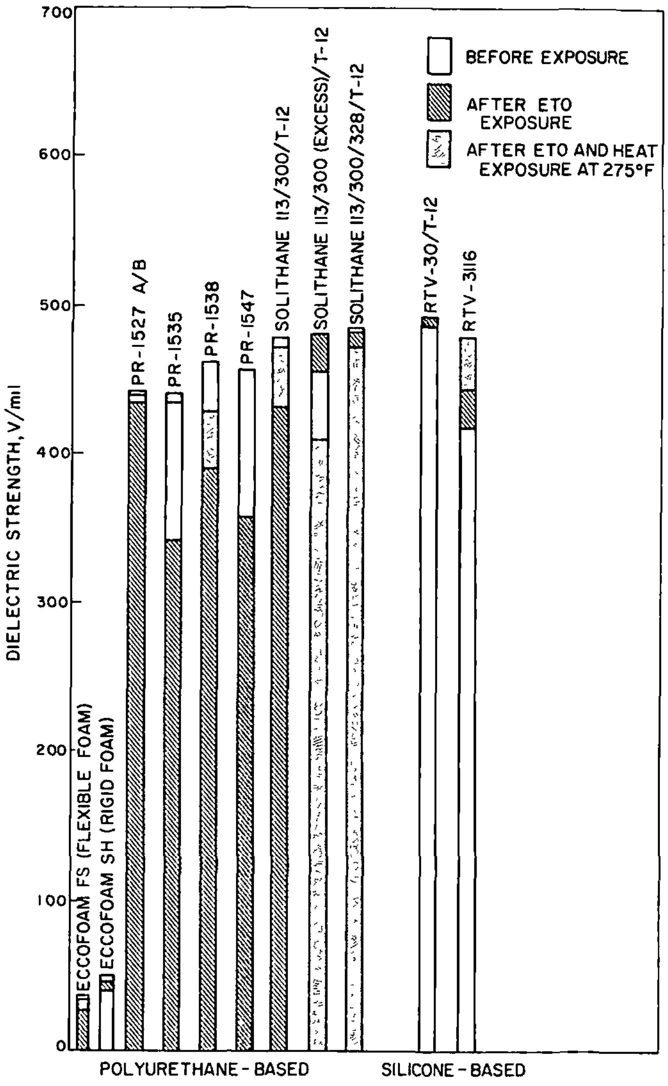

Fig. 11. Dielectric strength of Encapsulants at room temperature, before and after exposure to sterilization conditions

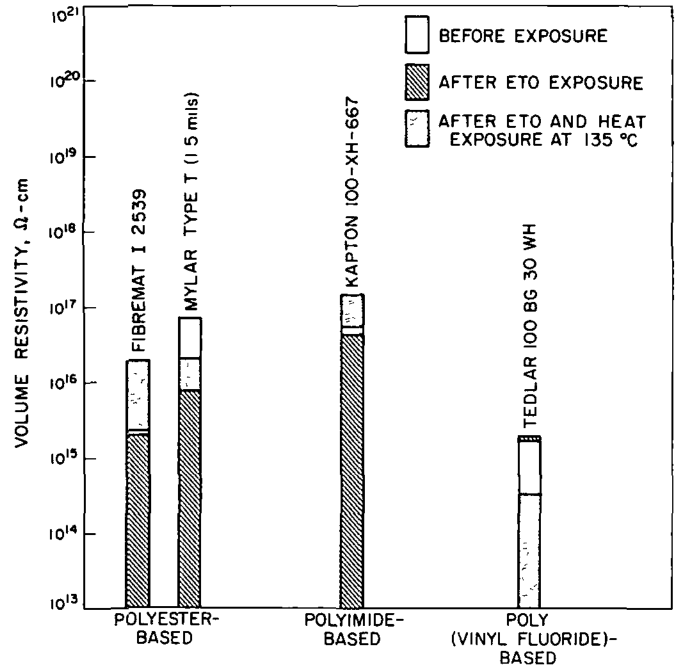

Fig. 12. Volume resistivities of Films at room temperature, before and after exposure to sterilization conditions

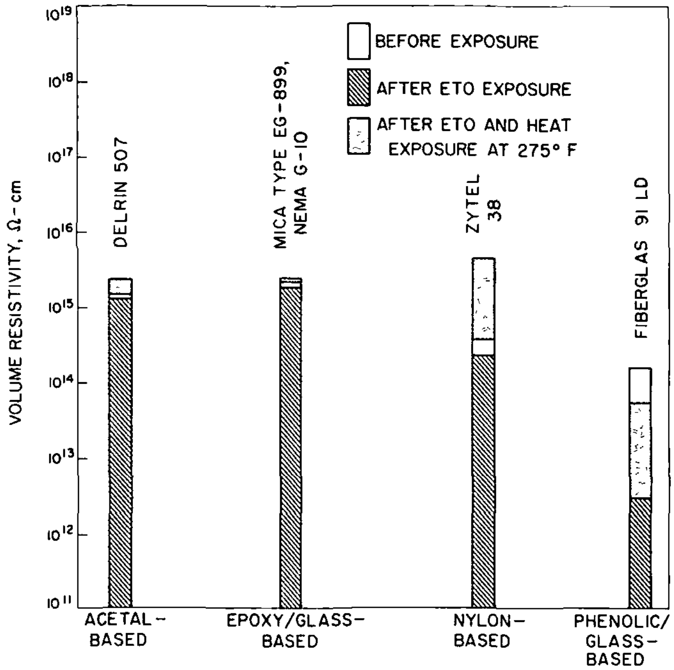

Fig. 14. Volume resistivities of Plastics at room temperature, before and after exposure to sterilization conditions

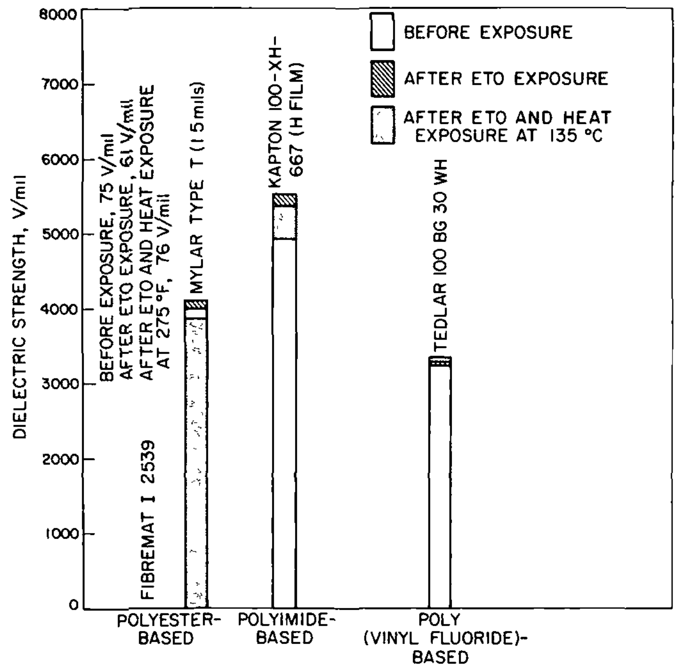

Fig. 13. Dielectric strength of Films at room temperature, before and after exposure to sterilization conditions

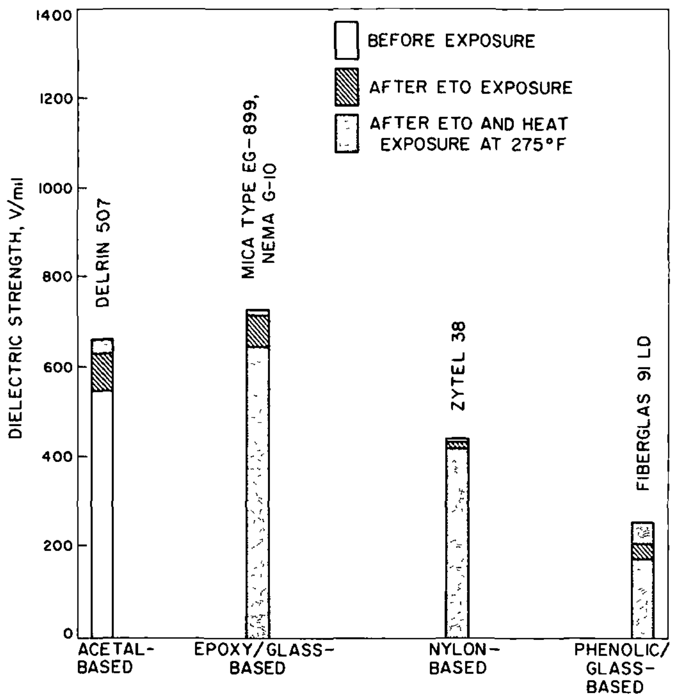

Fig. 15. Dielectric strength of Plastics at room temperature, before and after exposure to sterilization conditions

Table 17. Summary of test results for ETO decontamination procedure[a] on PLASTICS

No.	Commercial designation	Material type	Manufacturer	Mechanical properties						Electrical properties				Physical and thermal properties	
				Hardness		Tensile strength, psi		Elongation, %		Volume resistivity, Ω—cm		Dielectric strength, V/mil		Volume change, %	Weight change, %
				Control	Test	Control	Test	Control	Test	Control	Test	Control	Test		
1	Delrin 507	Acetal, UV stabilized	Du Pont	74.6D	78.6D	10,500	4,200	17.4	20	1.87×10^{15}	1.03×10^{15}	>553	>635	0	+1.616
2	Fiberglas 91 LD	Phenolic/glass	American Reinforced Plastics	B 79.5	B 81.3	34,000	35,600	2.3	2.0	1.94×10^{14}	4.4×10^{12}	186	203	+0.161	+0.089
3	Mica Type EG-899, NEMA G-10	Epoxy/glass	Mica Corp.	R 21	R 21 3	28,400	28,100	2.3	1.9	3.2×10^{15}	2.7×10^{15}	735	715	−0.026	−0.072
4	Zytel 38	Nylon 610	Du Pont	67.7D	71.8D	6,850	2,860	35.9	36	5.2×10^{14}	3.6×10^{14}	439	435	0	+2.015

[a]Six cycles of 28 h each at 50°C and 50 ±5% relative humidity.

Table 18. Summary of test results for ETO decontamination[a] and dry heat sterilization[b] procedure on PLASTICS

No.	Commercial designation	Mechanical properties							Electrical properties				Physical and thermal properties		Compatibility rating
		Hardness		Tensile strength, psi		Elongation, %		Creep[c]	Volume resistivity, Ω—cm		Dielectric strength, V/mil		Volume change, %	Weight change, %	
		Control	Test	Control	Test	Control	Test		Control	Test	Control	Test			
1	Delrin 507	74.6D	82.3D	10,500	4,200	17.4	25	Failed	1.87×10^{15}	3.3×10^{15}	>553	671	−1.84	−0.866	NC
2	Fiberglas 91 LD	B 79.5	B 87.2	34,000	33,700	2.3	2.0	Passed	1.94×10^{14}	7.2×10^{18}	186	>262	−0.119	−1.578	M
3	Mica Type EG-899, NEMA G-10	R 21	R 21.6	28,400	28,700	2.3	2.5	—	3.2×10^{15}	3.5×10^{15}	735	658	0	−0.390	C
4	Zytel 38	67.7D	79.4D	6,850	3,700	35.9	25	Failed	5.2×10^{14}	6.3×10^{15}	439	424	−1.40	−0.902	NC

[a]Six cycles of 28 h each at 50°C and 50 ±5% relative humidity.
[b]Six cycles of 92 h each at 135°C in dry nitrogen.
[c]Performed at 135°C in nitrogen atmosphere.

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Table 19. Changes in mechanical properties of PLASTICS after ETO decontamination and dry heat sterilization

Product and material type	After ETO exposure			After ETO and dry heat exposure at 135°C		
	Unit change in hardness	Tensile strength, % retained	Elongation, % retained	Unit change in hardness	Tensile strength, % retained	Elongation, % retained
Delrin 507 (Acetal)	+4	40	115	+7.7	40	144
EG-899 (G-10) (Epoxy/glass)	+0.3	99	83	+0.6	101	109
Zytel 38 (Nylon 610)	+4.1	42	100	+11.7	54	70
Fiberglas 91 LD (Phenolic/glass)	+1.8	105	87	+7.7	99	87

7. Tapes. Only one tape, Mystic 7452, was evaluated during the report period. A summary of test results after ETO–Freon and dry heat exposures is given in Tables 20 and 21. The aluminum tape seemed to improve its mechanical properties, such as peel adhesion and breaking strength, after exposure to both ETO–Freon 12 and to dry heat. The loss in dielectric strength that occurred after ETO exposure was more than regained after dry heat exposure (Table 21). The volume resistivity did not undergo significant changes (Fig. 16). The product was rated C.

8. Wire Enamels. Three different magnetic wires, with enamel finish, were also tested for sterilizability. The enamels were Alkenex (an alkyd polyester), Formex (a polyvinyl formal/phenolic) and Pyre ML (a polyimide).

The tests performed were limited in number and are indicated in Tables 22 and 23.

The usual weight gain after exposure to sterilant gas mixture was encountered. The absorbed gases were probably responsible for the reduction in scrape-adhesion. The standard scrape-adhesion tester could not be used on the wires; instead, the coating was scraped manually with a plastic spatula. The flexibility test consisted of flexing the wire a few times with the fingers and observing the effects under a microscope.

After the thermal sterilization, the Alkenex and Formex enamels could be scraped off by applying light-to-medium pressure with the spatula. The Pyre ML resisted such scraping. Flexing the wire resulted in some flaking of the Alkenex, and a slight flaking of the Formex, but had no effect on the Pyre ML. On the basis of these tests, the Pyre ML coating was rated C, and the other two, NC.

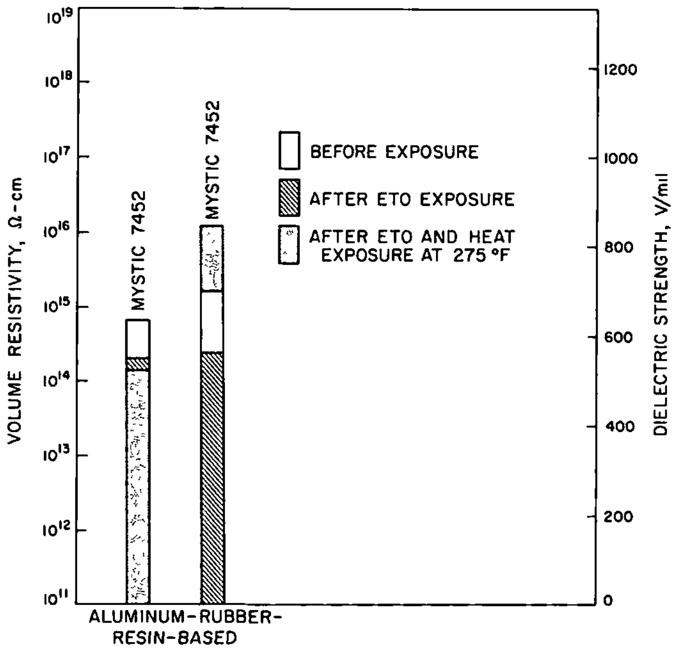

Fig. 16. Volume resistivity and dielectric strength of a Tape at room temperature, before and after exposure to sterilization conditions

It should be pointed out that the weight changes reported in Tables 22 and 23 are based on the total weight of wire and enamel. The contribution of the enamel to the total weight is probably about 2 to 2.5%. The weight losses in the table should, therefore, be multiplied by 40 to 50, to reflect the weight loss of the enamel.

Table 20. Summary of test results for ETO decontamination[a] procedure on TAPES

No.	Commercial designation	Material type	Manufacturer	Mechanical properties						Electrical properties				Physical and thermal properties	
				Peel adhesion, oz/in. width		Breaking strength, lb/in.		Elongation, %		Volume resistivity, Ω–cm		Dielectric strength, V/mil		Volume change, %	Weight change, %
				Control	Test	Control	Test	Control	Test	Control	Test	Control	Test		
1	Mystik 7452	Rubber resin/ aluminum	Mystik Tape Products	107.8	116.7	30	31	9.7	13.7	8.1×10^{14}	3.1×10^{14}	700	578	0	+0.137

[a]Six cycles of 28 h each at 50°C and 50 ±5% relative humidity.

Table 21. Summary of test results for ETO decontamination[a] and dry heat sterilization[b] procedure on TAPES

No.	Commercial designation	Mechanical properties						Electrical properties				Physical and thermal properties		Compatibility rating
		Peel adhesion, oz/in. width		Breaking strength, lb/in.		Elongation, %		Volume resistivity, Ω–cm		Dielectric strength, V/mil		Volume change, %	Weight change, %	
		Control	Test	Control	Test	Control	Test	Control	Test	Control	Test			
1	Mystik 7452	107.8	161.6	30	32	9.7	13	8.1×10^{14}	1.32×10^{14}	700	858	−1.004	−0.448	C

[a]Six cycles of 28 h each at 50°C and 50 ±5% relative humidity.

[b]Six cycles of 92 h each at 135°C in dry nitrogen.

Table 22. Summary of test results for ETO decontamination procedure on WIRE ENAMELS

No.	Commercial designation	Material type	Manufacturer	Flexibility		Weight change,[a] %	Comments
				Control	Test		
1	Alkenex—Heavy magnet wire; copper	Alkyd polyester	General Electric	Slight delamination	Passed	+0.152	Coating removed by light scraping after exposure
2	Formex—Heavy magnet wire; copper	Polyvinyl formal/ phenolic	General Electric	Passed	Passed	+0.688	As above
3	Pyre ML RK 692	Polyimide	Du Pont	Passed	Passed	+0.183	As above

[a]Percent net change in weight of wire and enamel.

Table 23. Summary of test results for ETO decontamination and dry heat sterilization procedure on WIRE ENAMELS

No.	Commercial designation	Material type	Flexibility		Weight change,[a] %	Comments	Compatibility rating
			Control	Test			
1	Alkenex—Heavy magnet wire; copper	Alkyd/polyester	Slight delamination	Passed	+0.013	Coating removed by medium scraping	M
2	Formex—Heavy magnet wire; copper	Polyvinyl formal/ phenolic	Passed	Passed	−0.007	Coating removed by medium scraping	M
3	Pyre ML RK 692	Polyimide	Passed	Passed	−0.031	Coating resistant to scraping	C

[a]Percent net change in weight of wire and enamel.

9. *General results.* Based on the criteria used in this report, about 29% of the polymeric products tested were rated *compatible* with the specified sterilization conditions; about 53% were rated *not compatible*; and the remaining 18% were considered *marginal.*

C. Results and Discussion of Materials Exposed to ETO–Freon 12 and Dry Heat at 120°C and 150°C

Five of the products that were exposed to environments according to the JPL specification were also exposed to 120° and 150°C in nitrogen after the usual ETO–Freon 12 decontamination. The exposure times were as follows:

(1) At 120°C, 6 cycles of 250 h each.

(2) At 150°C, 6 cycles of 59 h each.

These time–temperature conditions are considered the equivalent to 6 cycles of 92 h each at 135°C, and are based on *D-values* furnished by the National Aeronautics and Space Administration (NASA) (see footnote 2).

The five products tested were Solithane 1 (see Appendix C), RTV-30 cured with T-12 (or dibutyltindilaurate), Butyl 318-7, Fiberglas 91 LD, and Kapton 100.

Test specimens for Solithane, RTV-30, and Kapton were prepared, in each case, from a different batch than that used for the 135°C exposure. The Butyl and Fiberglas samples were prepared from the same batches for all temperature exposures.

A summary of test results is given in Tables 24, 25, and 26. Changes in properties, rather than the actual values obtained (see Appendix B for these), are given in Tables 24 and 25. Values obtained for 135°C exposure are included in these tables for comparative evaluation.

The data in Table 24 indicate that the elastomeric products Solithane 1 and Butyl 318-7 were more affected by exposure to the higher temperature for a shorter period (354 h, 150°C) than at a lower temperature for a longer period (1500 h, 120°C). The polyurethane showed

Table 24. Changes in mechanical properties after exposure of various durations to dry heat sterilization at various temperatures

Product and type of material	Change in hardness Shore or Rockwell			Tensile strength, psi % retained			Elongation, % retained		
	120°C (6 × 250 h)	135°C (6 × 92 h)	150°C (6 × 59 h)	120°C (6 × 250 h)	135°C (6 × 92 h)	150°C (6 × 59 h)	120°C (6 × 250 h)	135°C (6 × 92 h)	150°C (6 × 59 h)
Solithane 1 (polyurethane)	+1	−13	−20	68	60	38	119	144	137
RTV-30/T-12 (silicone)	+6	+3	+3	95	90	88	92	122	120
Butyl 318-7	−2	−4	−12	103	90	89	91	107	96
Fiberglas 91 LD (phenolic/glass)	+5	+8	+5	112	98	90	75	80	92
	Tear strength, % retained								
Kapton 100 (polyimide)	62	94	82	100	92	94	89	122	93

Table 25. Changes in percent weight and volume after exposure of various durations to dry heat sterilization at various temperatures

Product	Weight change, %			Volume change, %		
	120°C	135°C	150°C	120°C	135°C	150°C
Solithane 1	−0.380	+0.825	−1.759	−0.699	−0.731	Samples deformed
RTV-30/T-12	−0.357	−0 339	−0.445	−0.912	−0.561	−0.265
Butyl 318-7	−1.714	−1.969	−2.164	−1.869	−0.593	−2.381
Fiberglas 91 LD	−1.945	−1.578	−1.888	−1.193	−0.119	−2.197
Kapton 100	−0.159	−0.200	−0.131	−0.050	−0.398	−0.569

Table 26. Electrical properties after exposure of various durations to dry heat sterilization at various temperatures

Product and type of material	Volume resistivity, Ω—cm				Dielectric strength, V/mil			
	Control	120°C	135°C	150°C	Control	120°C	135°C	150°C
Solithane 1	8.1×10^{14}	2.3×10^{14}	2.54×10^{13}	2.2×10^{13}	>465	480	471	>427
RTV-30/T-12	3.17×10^{14}	3.7×10^{14}	7.32×10^{14}	1.04×10^{15}	486	456	491	>449
Fiberglas 91 LD	1.94×10^{14}	4.7×10^{13}	4.4×10^{12}	4.6×10^{13}	186	>347	203	>337
Kapton 100	1.12×10^{17}	1.03×10^{17}	1.2×10^{17}	$6\,9 \times 10^{16}$	4630	5720	5350	5070

considerable loss in hardness and tensile strength at 150°C, and is definitely incapable of being sterilized at this temperature. At 120°C its retained mechanical properties indicate that the material has marginal capability.

The property most affected in the Butyl rubber product, was hardness. As the exposure temperature rose from 120° to 150°C, the product became softer. No pronounced effects were noticed on its tensile properties by the change in the sterilization regimens.

The data also indicate that no important changes in the properties of Kapton 100, RTV-30, and Fiberglas 91 LD took place with changes of the sterilization conditions. The relatively low tear strength encountered with Kapton 100 after exposure at 120°C was unexpected and has no satisfactory explanation.

V. Conclusions

The ETO–Freon 12 decontamination procedure had its effects on the products tested, but in most cases these effects were not permanent. After the process of exposure to heat sterilization was completed, the losses in most properties were regained. In some products, however, the significant losses suffered after ETO decontamination could not be recovered. Examples of such products were Delrin 507, Zytel 38, PR-1547 and Eccofoam FS. It cannot be said with certainty, however, that the failure of these products was due to the permanent effects of the ETO decontamination. They might have failed by exposure to the dry heat alone.

The weight gains encountered in the majority of cases after ETO–Freon 12 exposure were due to absorption of the sterilant gas mixture; and desorption took place after exposure to dry heat. The positive weight change in a few of the products, even after thermal exposure, suggested the possibility of a reaction between ETO and the active functional groups present in the products.

After the dry heat exposure, a number of products were rated *not compatible* because of weight loss. In many of the products, the mechanical and physical properties were not affected because of this loss of material. This is an indication of the absence of polymer degradation. The weight loss was due, rather, to the volatilization of low-molecular weight processing or compounding ingredients, such as plasticizers, diluents, antioxidants, and so forth. Before sterilization, a thermal–vacuum pretreatment could reduce the amount of volatilizable products.

The investigation of the effects of other dry heat sterilization temperatures, carried out with a limited number of compounds, shows that products that resist high temperature exposure for a shorter period of time (e.g., 150°C for 354 h) will resist longer exposure at a lower temperature (e.g., 120°C for 1500 h). Also a product stands a better chance for heat sterilization at a lower temperature, although the exposure period may, of necessity, be long.

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Appendix A

Complete Data on ETO and Dry Heat Sterilization at 135°C

Table A-1. Complete test results for ETO decontamination and dry heat sterilization on ADHESIVES

Commercial designation	Cure schedule for unheated controls		Exposure conditions	Mechanical properties				Thermal properties
	Duration, h	Temperature, °F		Hardness, Shore	Stressed dimensions, in.	Shear strength, psi	Creep	Weight change, %
Adhesives, Structural								
EC-1614 B/A	1/4	200	Control	69.7D	0.99/1.01	1325		
					0.99/1.01	1450		
					0.99/1.00	1485		
					1.00/1.00	1405		
				(av) 69.7D		(av) 1420		
			After ETO exposure	69.3D	0.99/0.99	1420		+2.951
					0.99/0.99	1060		+2.305
					1.01/1.00	1260		+2.816
					1.01/0.99	1425		
					0.99/0.99	1200		
				(av) 69.3D		(av) 1270		(av) +2.691
			After ETO and thermal exposure	68.7D	1.01/0.99	2000	Failed	+0.380
					0.99/0.99	1710		+0.132
					1.00/1.00	1540		
					1.00/0.99	1760		
					0.99/0.99	1620		
				(av) 68.7D		(av) 1730		(av) +0.256
EC-2216 B/A	2	150	Control	53 D	1.00/1.00	1290		
				55 D	1.00/1.00	1180		
				50.7D	1.00/1.00	970		
					1.01/0.99	915		
					1.00/0.99	780		
				(av) 52.9D		(av) 1030		
			After ETO exposure	43.7D	1.00/0.99	680		+2.052
				42.7D	0.99/0.99	780		+2.590
				43 D	1.00/1.00	630		+2.110
					1.01/1.00	790		
				(av) 43.1D		(av) 720		(av) +2.251
			After ETO and thermal exposure	50 D	1.00/0.99	1810	Failed	+0.196
				49.3D	1.00/0.99	2120		+0.319
				53.7D	1.02/0.99	1920		+0.149
					1.00/1.00	1990		
					1.01/0.99	2350		
				(av) 51.0D		(av) 2040		(av) +0.221
Eccobond 45/15	16	125	Control	60.3D	1.00/1.00	1120		
				60.3D	1.00/1.00	1430		
				59.7D	1.01/1.00	1360		
					1.00/1.00	1300		
				(av) 60.1D		(av) 1303		

Table A-1 (contd)

Commercial designation	Cure schedule for unheated controls: Duration, h	Cure schedule for unheated controls: Temperature, °F	Exposure conditions	Mechanical properties: Hardness, Shore	Mechanical properties: Stressed dimensions, in.	Mechanical properties: Shear strength, psi	Mechanical properties: Creep	Thermal properties: Weight change, %
Adhesives, Structural (contd)								
			After ETO exposure	35 D	1.01/0.99	920		+9.762
				40.7D	1.00/1.00	550		+8.831
				35 D	1.00/0.99	730		+10.005
					1.01/1.00	990		
				(av) 36.9D		(av) 800		(av) +9.533
			After ETO and thermal exposure	44.3D	1.01/1.00	2200	Failed	
					1.03/1.00	2190		
					1.01/0.99	1860		
					1.03/0.99	1920		
					1.02/1.00	2210		
				(av) 44.3D		(av) 2080		
Adhesives, Nonstructural								
4684/RC-805	1/12	300 at 25 psi	Control	39 A	1.03/1.01	140		
				44.3A	1.03/1.01	150		
					1.05/1.02	140		
					1.07/1.02	150		
				(av) 41.7A		(av) 145		
			After ETO exposure	32.3A	1.02/1.02	[a]		−3.168
				49 A	1.05/1.00	[a]		−2.441
					1.06/1.00	150		
					1.03/1.01	120		
					1.06/1.01	120		
				(av) 40.7A		(av) 130		(av) −2.805
			After ETO and thermal exposure	70 A	1.04/1.00	150[a]		−10.520
				70 A	1 03/1.00	160[a]		−10.505
					1.03/1.00	160[a]		
					1.04/0.99	150[a]		
					1.02/1 00	160[a]		
				(av) 70 A		(av) 156[a]		(av) −10.513
46950	1/12	300 at 25 psi	Control	Sample not adaptable to shore hardness test	1.04/1.00	80		
					1.01/1.00	90		
					1.01/1.00	70		
					1.02/1.00	110		
					1.01/1.01	130		
						(av) 100		
			After ETO exposure	↓	1.03/1.00	120		−5.144
					1.07/1.00	140		−6.387
					1.01/1.01	90		−6.785
					1.01/1.01	90		
					1.01/1.01	120		
						(av) 110		(av) −6.102

Table A-1 (contd)

Commercial designation	Cure schedule for unheated controls		Exposure conditions	Mechanical properties				Thermal properties
	Duration, h	Temperature, °F		Hardness, Shore	Stressed dimensions, in.	Shear strength, psi	Creep	Weight change, %
Adhesives, Nonstructural (contd)								
			After ETO and thermal exposure	↓	1.01/1.00	160[a]		−8.625
					1.01/1.00	160[a]		−9.770
					1.01/1.00	130[a]		−9.286
					0.99/1.00	130[a]		
					1.00/1.00	110[a]		
						(av) > 138[a]		(av) −9.227
RTV-40/T-12	24	75	Control	32.6A	1.02/1.00	200		
	24	275		34 A	1.01/1.00	90		
				35.6A	1.01/1.00	210		
				(av) 34.1A		(av) 167		
			After ETO exposure	30.3A	0.99/1.00	150		+0.354
				30.3A	0.99/1.00	150		+0.450
				30.3A	0.99/1.00	90		+0.363
					0.99/1.00	140		
				(av) 30.3A		(av) 133		(av) +0.389
			After ETO and thermal exposure	38 A	1.01/1.00	340		−0.587
				40.3A	1.00/1.00	310		−0.870
				42 A	1.00/1.00	300		−0.526
					1.00/1.00	300		
					1.00/0.99	310		
				(av) 40.1A		(av) 310		(av) −0.661

[a]Mylar panel fractured before adhesive failed.

Table A-2. Complete test results for ETO decontamination and dry heat sterilization on COATINGS

Commercial designation	Cure schedule for unheated controls		Exposure conditions	Mechanical properties		Electrical properties		
	Duration, h	Temperature, °F		Scrape adhesion, kg	Flexibility (cold cracking)	Thickness, mil	Volume resistivity, Ω—cm	Dielectric strength, V/mil
Chemlock 607	24	Room temperature	Control	1.7	Failed	0.08	2.5×10^{10}	
				0.8	Failed		Shorted	
				0.8			Shorted	
				(av) 1.1	(av) Failed		(av) 2.5×10^{10}	
			After ETO exposure	Failed	Failed	0.67	2.7×10^{12}	313
				Failed	Failed	0.43	2.1×10^{14}	163
				Failed	Failed	0.47	2.4×10^{13}	319
				(av) Failed	(av) Failed		(av) 7.89×10^{13}	(av) 265

Table A-2 (contd)

Commercial designation	Cure schedule for unheated controls: Duration, h	Cure schedule for unheated controls: Temperature, °F	Exposure conditions	Mechanical properties: Scrape adhesion, kg	Mechanical properties: Flexibility (cold cracking)	Electrical properties: Thickness, mil	Electrical properties: Volume resistivity, Ω—cm	Electrical properties: Dielectric strength, V/mil
			After ETO and thermal exposure	Failed	Failed	0.47	2.0×10^{15}	362
				Failed	Failed	0.31	5.6×10^{15}	388
				Failed	Failed	0.35	1.3×10^{15}	485
				(av) Failed	(av) Failed		(av) 3.0×10^{15}	(av) 412
SS-4004	24	Room temperature	Control	0.5	Failed	0.53	15.0×10^{15}	896
				0.5	Failed	0.35	2.0×10^{15}	1057
				0.5	Failed	0.62	7.9×10^{15}	775
				(av) 0.5	(av) Failed		(av) 8.3×10^{15}	(av) 909
			After ETO exposure	2.0	Passed	0.40	5.0×10^{10}	1125
				1.0	Passed	0.27	8.3×10^{10}	1703
				2.0	Passed	0.43	Poor contact	1045
				(av) 1.7	(av) Passed		(av) 6.7×10^{10}	(av) 1291
			After ETO and thermal exposure	2.7	Passed	0.24	15.0×10^{13}	1710
				1.0	Passed	0.43	8.3×10^{13}	1070
				2.8	Passed	0.28	Poor contact	1520
				(av) 2.2	(av) Passed		(av) 1.17×10^{14}	(av) 1430
SS-4101	24	Room temperature	Control	1.0	Passed	0.65	6.3×10^{14}	215
				1.0	Passed	0.93	3.0×10^{12}	140
				1.0	Passed	0.68	Shorted	265
				(av) 1.0	(av) Passed		(av) 3.3×10^{14}	(av) 207
			After ETO exposure	0.5	Passed	0.49	4.0×10^{10}	815
				0.5	Passed	0.72	3.0×10^{13}	470
				0.5	Passed	0.22	Shorted	Shorted
				(av) 0.5	(av) Passed		(av) 1.5×10^{13}	(av) 643
			After ETO and thermal exposure	0.5	Failed	0.35	6.4×10^{14}	1000
				3.5	Failed	0.49	Poor Contact	710
				1.5	Failed			
				(av) 1.8	(av) Failed		(av) 6.4×10^{14}	(av) 855
SS-4044	24	Room temperature	Control	0.5	Failed	0.57	15.5×10^{13}	755
				0.5	Failed	0.52	5.4×10^{13}	808
				0.5	Failed			
				(av) 0.5	(av) Failed		(av) 1.04×10^{14}	(av) 782
			After ETO exposure	0.5	Failed	0.56	Shorted	307
				0.5	Failed	0.65	Shorted	270
				0.5	Failed	0.57	1.65×10^{14}	351
				(av) 0.5	(av) Failed		(av) 1.65×10^{14}	(av) 309
			After ETO and thermal exposure	3.5	Failed			
				3.5	Failed			
				3.5	Failed			
				(av) 3.5	(av) Failed			

Table A-3. Complete test results for ETO decontamination and dry heat sterilization on ELASTOMERS

Commercial designation	Exposure conditions	Mechanical properties										Physical and thermal properties	
		Hardness, Shore	Tensile bars			Rings			Compression set			Volume change, %	Weight change, %
			Stressed dimensions, in.	Tensile strength, psi	Elongation, %	Stressed dimensions, in.	Tensile strength, psi	Elongation, %	t_0	t_1	% Compression set, $\frac{t_0 - t_1}{t_0 - t_s} \times 100$		
Butyl 318-7	Control	72.3A	0 140/0.480	1620	300	0.126/0 072	1650	280					
		72.4A	0.136/0.480	1640	300	0.124/0.072	1820	310					
		72 8A	0.141/0.480	1600	300	0.127/0.070	1560	260					
						0.121/0.071	1800	250					
		(av) 72.5A		(av) 1620	(av) 300		(av) 1710	(av) 275					
	After ETO exposure	67 A	0.482/0.139	1700	300	0.131/0.075	1500	310				0	+0.936
		67 6A	0.483/0.140	1510	300	0.129/0.076	1500	330				+0 300	+0.973
		66.6A	0.483/0.140	1580	350	0.129/0.076	1480	330					+0 873
						0.133/0.076	1520	360					
		(av) 67.1A		(av) 1600	(av) 317		(av) 1500	(av) 333				(av) +0.150	(av) +0.927
	After ETO and thermal exposure	68.7A	0.478/0.138	1560	350	0.130/0.076	1530	280	0.516	0.412	74.3	−0.660	−2.038
		68.3A	0.481/0.139	1510	300	0.130/0.076	1540	300	0.516	0.411	75.0	−0.525	−1.995
		67.5A	0.479/0.140	1510	300	0.130/0.076	1590	300	0.513	0.410	75.2		−1.874
						0.130/0.077	1500	300	0.506	0.409	74.6		
		(av) 68.2A		(av) 1530	(av) 317		(av) 1540	(av) 295			(av) 74.8	(av) −0.593	(av) −1.969

Table A-4. Complete test results for ETO decontamination and dry heat sterilization on ENCAPSULANTS

Commercial designation	Cure schedule for unheated controls		Exposure conditions	Mechanical properties					Electrical properties			Physical and thermal properties	
	Duration, h	Temperature, °F		Hardness, Shore	Stressed dimensions, in.	Tensile strength, psi	Elongation, %	Peel strength, lb/in. of width	Thickness, mil	Volume resistivity, Ω–cm	Dielectric strength, V/mil	Volume change, %	Weight change, %
PR 1527 A/B	16	200	Control	77.3A	0.099/0.481	1890	500	1.4	100.1	1.47×10^{12}	439		
				79 A	0.102/0.481	1880	600	0.9	100.2	1.44×10^{12}	424		
				79.2A	0.100/0.478	2130	550	1.4	100.2	9.20×10^{11}	449		
								1.3					
								1.0					
				(av) 78.5A		(av) 1970	(av) 550	(av) 1.2		(av) 1.28×10^{12}	(av) 437		
			After ETO exposure	77.5A	0.101/0.483	1640	550	Failed	100.3	3.30×10^{11}	419	+0.906	+0.867
				78 A	0.101/0.480	1750	550		100.5	4.00×10^{11}	452	+0.803	+0.578
				78.2A	0.100/0.483	1700	600		100.2	4.02×10^{11}	454	+0.607	+0.501
				(av) 77.9A		(av) 1700	(av) 570			(av) 3.77×10^{11}	(av) 441	(av) +0.772	(av) +0.649
			After ETO and thermal exposure	61 A		Failed	Failed	Failed	100.0	6.6×10^{11}	445	Deformed	−1.595
				61 A					100.0	1.51×10^{12}	455	−0.803	−1.001
				61 A					100.1	1.05×10^{12}	425	Deformed	−1.321
				(av) 61 A						(av) 1.07×10^{12}	(av) 442	(av) −0.803	(av) −1.306
PR 1535	8	180	Control	88 A		1690			99	6.9×10^{11}	455		
				88 A		1770	520		100	6.4×10^{11}	420		
				88 A		1670	570		102	3.9×10^{11}	426		
				(av) 88 A		(av) 1710	(av) 545			(av) 5.7×10^{11}	(av) 434		
			After ETO exposure	88 A		1950	480		140	5.7×10^{12}	>343	+0.986	+1.44
				88 A		1820	460		143	5.6×10^{12}	336	+1.148	+1.43
				88 A		1680	410		134	5.0×10^{12}	>345		+1.41
													+1.30
													+1.25
													+1.30
				(av) 88 A		(av) 1820	(av) 450			(av) 5.4×10^{12}	(av) >341	(av) +1.067	(av) +1.355
			After ETO and thermal exposure	82.5A		3160	530		104	4.1×10^{12}	456	+0.682	−0.439
				85 A		>2550	>620		104	4.8×10^{12}	447	+0.076	−0.321
				85 A		2750	650		105	4.5×10^{12}	419	+0.990	−0.308
				(av) 84.1A		(av) >2820	(av) >600			(av) 4.5×10^{12}	(av) 441	(av) +0.583	(av) −0.356

Table A-4 (contd)

Commercial designation	Cure schedule for unheated controls		Exposure conditions	Mechanical properties					Electrical properties			Physical and thermal properties	
	Duration, h	Temperature, °F		Hardness, Shore	Stressed dimensions, in.	Tensile strength, psi	Elongation, %	Peel strength, lb/in. of width	Thickness, mil	Volume resistivity, Ω–cm	Dielectric strength, V/mil	Volume change, %	Weight change, %
PR 1538	8	180	Control	77 A	0.101/0.488	1080	590		100	2.4×10^{13}	>480		
				77 A					99	2.1×10^{13}	455		
				77 A	0.101/0.488	974	540		99	2.6×10^{13}	450		
				(av) 77 A		(av) 1027	(av) 565			(av) 2.4×10^{13}	(av) >462		
			After ETO exposure	74.5A	0.130/0.485	952	710		131	1.2×10^{13}	359	+0.525	+1.79
				73.5A	0.131/0.484	946	710		107	9.0×10^{12}	>448	+0.535	+1.60
				74.5A	0.131/0.489	952	700		132	9.0×10^{12}	>364	+0.613	+1.78
				(av) 74.2A		(av) 950	(av) 707			(av) 1.0×10^{13}	(av) >390	(av) +0.558	(av) +1.72
			After ETO and thermal exposure	74 A	0.130/0.490	895	825		103	8.7×10^{13}	456	+0.366	−0.468
				74 A	0.129/0.484	817	800		103	5.8×10^{12}	456	+0.258	−0.500
				74 A	0.129/0.488	858	900		130	6.6×10^{12}	>369	0	−0.443
				(av) 74 A		(av) 857	(av) 842			(av) 7.0×10^{12}	(av) >427	(av) +0.208	(av) −0.470
PR 1547	8	180	Control	81 A	0.099/0.485	2000	540		99	3.5×10^{13}	>485		
				81 A	0.100/0.485	1810	500		99	3.5×10^{13}	394		
				80 A					98	3.4×10^{13}	>490		
				(av) 81 A		(av) 1905	(av) 520			(av) 3.5×10^{13}	(av) >456		
			After ETO exposure	72 A	0.143/0.485	1100	700		138	2.6×10^{13}	>348	+2.935	+1.68
				71.5A	0.141/0.487	1120	700		132	2.1×10^{13}	>364	+4.253	+1.51
				71 A	0.136/0.487	1280	590		135	2.3×10^{13}	>356	+4.475	+1.49
				(av) 71.5A		(av) 1167	(av) 663			(av) 2.3×10^{13}	(av) >356	(av) +3.888	(av) +1.57
			After ETO and thermal exposure	77 A	0.143/0.485	949	875		133	1.04×10^{13}	>361	+1.187	−0.751
				78 A	0.134/0.484	977	925		135	1.14×10^{13}	>356	+3.059	−0.725
				72 A	0.144/0.484	772	550		136	7.3×10^{12}	>353	+3.072	−0.721
				(av) 75.6A		(av) 899	(av) 783			(av) 9.7×10^{12}	(av) >357	(av) +2.439	(av) −0.732
RTV-30/T-12	24	75	Control	51.7A	0.099/0.468	466	90	2.6	98.5	4.42×10^{14}	476		
	24	275		54.7A	0.100/0.468	607	90	3.0	97.6	4.22×10^{14}	488		
				53.7A				2.7	97.3	3.87×10^{14}	494		
								2.9					
								2.7					
				(av) 55 A		(av) 536	(av) 90	(av) 2.8		(av) 4.17×10^{14}	(av) 486		
			After ETO exposure	54.3A	0.099/0.477	424	80	3.0	98.8	2.65×10^{14}	>486	−0.207	+0.304
				55 A	0.100/0.476	506	110	3.1	97.7	2.16×10^{14}	492	−0.624	+0.299
				55.3A	0.101/0.476	497	100	3.3	97.7	2.30×10^{14}	492	−0.208	+0.389
								3.1					
								2.7					
				(av) 54.9A		(av) 476	(av) 97	(av) 3.0		(av) 2.37×10^{14}	(av) >490	(av) −0.346	(av) +0.331
			After ETO and thermal exposure	58 A	0.099/0.476	531	110	2.6	97.0	6.43×10^{14}	490	−0.674	−0.313
				53 A	0.099/0.476	528	110	2.7	95.7	7.75×10^{14}	503	−0.457	−0.319
				57.3A				2.4	95.0	7.78×10^{14}	480	−0.552	−0.384
								2.8					
								2.5					
				(av) 57.8A		(av) 530	(av) 110	(av) 2.6		(av) 7.32×10^{14}	(av) 491	(av) −0.561	(av) −0.339

Table A-4 (contd)

Commercial designation	Cure schedule for unheated controls		Exposure conditions	Mechanical properties					Electrical properties			Physical and thermal properties	
	Duration, h	Temperature, °F		Hardness, Shore	Stressed dimensions, in.	Tensile strength, psi	Elongation, %	Peel strength, lb/in. of width	Thickness, mil	Volume resistivity, Ω–cm	Dielectric strength, V/mil	Volume change, %	Weight change, %
RTV-3116 (Formerly RTV-881)	24	75	Control	32.3A	0.099/0.475	225	160	0.45	97.3	6.04×10^{12}	483		
	24	275		32.7A	0.099/0.478	201	160	0.43	97.0	4.86×10^{12}	443		
				32.3A	0.098/0.475	185	150	0.38	97.8	5.18×10^{12}	424		
								0.29					
								0.32					
				(av) 32.4A		(av) 204	(av) 157	(av) 0.37		(av) 5.36×10^{12}	(av) 450		
			After ETO exposure	32.3A	0.101/0.478	292	150	0.35	97.3	8.10×10^{11}	478	+3.325	−0.917
				30.3A	0.097/0.478	198	130	0.25	96.5	5.73×10^{11}	384	+5.438	−0.638
				31.8A	0.097/0.478	261	140	0.44	97.3	9.65×10^{11}	467	+1.951	−0.918
								0.32					
								0.35					
				(av) 31.5A		(av) 250	(av) 140	(av) 0.34		(av) 7.83×10^{11}	(av) 443	(av) +3.571	(av) −0.824
			After ETO and thermal exposure	44 A	0.098/0.460	166	110	0.31	97.0	2.23×10^{12}	480	+3.448	−3.184
				43.8A	0.098/0.463	156	100	0.32	94.5	2.68×10^{12}	477	+7.416	−3.162
				44.7A				0.89	95.3	3.16×10^{12}	477	+5.731	−3.154
								0.34					
								0.54					
				(av) 44.2A		(av) 161	(av) 105	(av) 0.48		(av) 2.69×10^{12}	(av) 478	(av) +5.532	(av) −3.167
Solithane 1/T-12	5	165	Control	60 A	0.101/0.474	405	90	0.64	99.3	9.90×10^{14}	>484		
				58.3A	0.100/0.480	427	90	1.35	101.7	1.00×10^{15}	452		
				58.3A	0.100/0.478	406	90	0.74	96.5	9.90×10^{14}	>498		
								0.94					
								0.97					
				(av) 58.9A		(av) 413	(av) 90	(av) 0.93		(av) 9.93×10^{14}	(av) >478		
			After ETO exposure	61.3A	0.105/0.478	408	90	0.42	97.2	1.43×10^{14}	>494	−0.200	+2.551
				60.3A	0.105/0.483	375	90	0.40	96.5	1.10×10^{14}	431	−0.298	+2.526
				60 A	0.104/0.481	440	100	0.46	103.5	1.42×10^{14}	368		+2.535
								0.74					
								0.39					
				(av) 60.5A		(av) 408	(av) 93	(av) 0.48		(av) 1.32×10^{14}	(av) >431	(av) −0.249	(av) +2.538
			After ETO and thermal exposure	45.3A	0.104/0.478	185	110	Failed	103.5	2.40×10^{13}	445	0	
				46 A	0.104/0.472	273	150		96.5	2.44×10^{13}	493	−1.892	
				46 A	0.106/0.480	281	130		97.2	2.79×10^{13}	474	−0.301	
				(av) 45.8A		(av) 246	(av) 130			(av) 2.54×10^{13}	(av) 471	(av) −0.731	

Table A-4 (contd)

Commercial designation	Cure schedule for unheated controls		Exposure conditions	Mechanical properties					Electrical properties			Physical and thermal properties	
	Duration, h	Temperature, °F		Hardness, Shore	Stressed dimensions, in.	Tensile strength, psi	Elongation, %	Peel strength, lb/in of width	Thickness, mil	Volume resistivity, Ω–cm	Dielectric strength, V/mil	Volume change, %	Weight change, %
Solithane 4/T-12	5	165	Control	55.3A	0.102/0.484	250	60	0.35	99.6	9.0 × 10^{13}	417		
				56.3A	0.099/0.484	210	70	0.45	100.5	8.45 × 10^{13}	477		
				57 A	0.099/0.482	220	70	0.69	99.2	8.80 × 10^{13}	474		
								0.19					
								0.46					
				(av) 56.2A		(av) 230	(av) 67	(av) 0.43		(av) 8.75 × 10^{13}	(av) 456		
			After ETO exposure	56.3A	0.100/0.487	220	70	0.15	101.7	1.56 × 10^{13}	467	+1.820	+2.414
				56 A	0.101/0.489	250	80	0.32	98.0	1.95 × 10^{13}	>490	+0.497	+2.407
				56.3A	0.102/0.483	240	80	0.39	98.5	1.53 × 10^{13}	>487	+1.102	+2.586
								0.27					
								0.20					
				(av) 56.2A		(av) 240	(av) 77	(av) 0.27		(av) 1.68 × 10^{13}	(av) >481	(av) +1.140	(av) +2.469
			After ETO and thermal exposure	41.3A	0.099/0.484	150	140	Failed	98.8	1.02 × 10^{13}	324	−0.199	+0.841
				41.8A	0.101/0.486	190	160		96.5	8.30 × 10^{12}	476	−0.401	+0.846
				44 A	0.101/0.486	180	140		97.0	1.22 × 10^{13}	428		+1.010
				(av) 42.4A		(av) 170	(av) 145			(av) 1.02 × 10^{13}	(av) 409	(av) −0.300	(av) +0.899
Solithane 12/T-12	5	165	Control	68 A	0.100/0.475	2100	140	22	100.5	1.49 × 10^{15}	462		
				68 A	0.099/0.479	1800	140	11	98.7	1.49 × 10^{15}	482		
				68 A	0.101/0.478	2200	130						
				(av) 68 A		(av) 2030	(av) 137	(av) 17		(av) 1.49 × 10^{15}	(av) 472		
			After ETO exposure	71 A	0.100/0.479	1900	140	9.2	100.5	8.24 × 10^{14}	>478	+0.913	+1.006
				70 A	0.100/0.479	1900	140	6.0	98.7	8.48 × 10^{14}	481	+1.017	+1.092
				70 A	0.100/0.481	2000	140	6 6	99.2	9.65 × 10^{14}	>484	+1.452	+1.245
								5.7					
				(av) 70.3A		(av) 1930	(av) 140	(av) 6.9		(av) 8.79 × 10^{14}	(av) >481	(av) +1.127	(av) +1.114
			After ETO and thermal exposure	68.8A	0.481/0.100	1440	130	30.7	100.0	1.16 × 10^{15}	470	−0.203	−1.298
				67.8A	0.476/0.099	1640	160	19.3	99.5	1.22 × 10^{15}	473		−1.287
				67.3A					101.0	1.35 × 10^{15}	470	+0.103	−1.161
				(av) 68 A		(av) 1540	(av) 145	(av) 25.0		(av) 1.24 × 10^{15}	(av) 471	(av) −0.050	(av) −1.249

Table A-5. Complete test results for ETO decontamination and dry heat sterilization on FILMS

Commercial designation	Exposure conditions	Mechanical properties: Tensile strength and elongation: Stressed dimensions, in.	Tensile strength, psi	Elongation, % (in 3.5 in.)	Tear strength: Thickness, mil	Tear strength, lb/mil	Electrical properties: Thickness, mil	Volume resistivity, Ω–cm	Dielectric strength, V/mil	Physical and thermal properties: Volume change, %	Weight change, %
Kapton 100-XH-667	Control	0.49/0.0011	14700	4.9	1.2	0.58	1.2	1.0 × 10^17	4200		
		0.48/0.0012	14200	7.4	1.2	0.54	1.2	7.0 × 10^16	5280		
		0.49/0.0012	12000	7.3	1.2	0.67	1.2	5.5 × 10^16	5480		
		0.49/0.0012	14000	7.9	1.2	0.44					
			(av) 13700	(av) 6.8		(av) 0.56		(av) 7.5 × 10^16	(av) 4930		
	After ETO exposure	0.50/0.0012	11600	7.7	1.2	0.46	1.2	8.4 × 10^16	5100	−0.245	+1.078
		0.50/0.0013	10800	7.9	1.1	0.69	1.1	5.5 × 10^16	5740	−0.050	+0.978
		0.49/0.0012	12100	7.7	1.2	0.60	1.1	5.4 × 10^16	5780	−0.371	+0.951
											+0.815
											+0.975
			(av) 11500	(av) 7.8		(av) 0.58		(av) 6.4 × 10^16	(av) 5540	(av) −0.222	(av) +0.959
	After ETO and thermal exposure	0.50/0.0011	16800	10.7	1.2	0.62	1.2	1.0 × 10^17	5330	−0.498	−0.259
		0.48/0.0012	9760	5.3	1.2	0.50	1.2	1.3 × 10^17	5240	−0.297	−0.214
		0.49/0.0011	8200		1.2	0.50	1.2	1.3 × 10^17	5480		−0.127
		0.49/0.0011	14400	7.7	1.2	0.53					
		0.50/0.0012	14300	9.4							
			(av) 12700	(av) 8.3		(av) 0.54		(av) 1.2 × 10^17	(av) 5350	(av) −0.398	(av) −0.200
Mylar Type T	Control	0.49/0.0011	10200	—	1.3	1.35	1.6	11.1 × 10^16	3380		
		0.49/0.0012	10200	14.3	1.4	1.19	1.4	8.9 × 10^16	4000		
		0.49/0.0011	10600	7.1	1.3	1.35	1.2	5.8 × 10^16	4500		
		0.49/0.0011	11000	10.6							
			(av) 10500	(av) 10.7		(av) 1.30		(av) 8.6 × 10^16	(av) 3960		
	After ETO exposure	0.49/0.0012	10900	8.4	1.3	1.11	1.4	17.4 × 10^15	4000	0	+1.366
		0.49/0.0012	10800	4.5	1.4	1.11	1.4	3.9 × 10^15	4220	0	+2.451
					1.6	1.01	1.3	5.5 × 10^15	4000	0	+2.457
			(av) 10850	(av) 6.5		(av) 1.08		(av) 8.9 × 10^15	(av) 4070	(av) 0	(av) +2.091
	After ETO and thermal exposure	0.43/0.0011	14900	6.4	1.0	1.55	1.6	7.8 × 10^16	3720	Wrinkles	+0.329
		0.43/0.0011	14700	5.7	1.1	1.64	1.5	3.0 × 10^15	4030	Wrinkles	+0.048
		0.44/0.0012	13100	6.7	1.2	1.17	1.3	1.0 × 10^16	3800	Wrinkles	+0.578
			(av) 14200	(av) 6.3		(av) 1.45		(av) 3.0 × 10^16	(av) 3850	(av) Wrinkles	(av) +0.318
Tedlar 100 BG 30 WH	Control	0.50/0.0010	10700	45.7	1.1	1.45	1.0	1.6 × 10^15	3330		
		0.50/0.0010	10600	44.3	1.0	0.86	0.9	3.3 × 10^15	3530		
		0.50/0.0010	12000	60.0	1.0	0.98	1.1	2.2 × 10^15	2980		
		0.50/0.0010	10400	39.4	1.0	1.60					
			(av) 10925	(av) 47.4		(av) 1.22		(av) 2.4 × 10^15	(av) 3280		
	After ETO exposure	0.50/0.0010	10000	34.3	1.1	0.81	1.1	2.0 × 10^15	2960	−0.173	−0.657
		0.50/0.0010	10900	41.4	1.1	0.81	1.0	3.0 × 10^15	3360	−0.202	−0.669
		0.50/0.0009	[illegible]	35.7	1.0	1.02	0.9	9.0 × 10^14	3600	−0.099	−0.684
		0.50/0.0010	9200	25.7	1.0	1.32					−0.639
		0.50/0.0010	10900	40.0							−0.409
											−0.299
			(av) 10500	(av) 35.4		(av) 0.99		(av) 2.0 × 10^15	(av) 3310	(av) −0.158	(av) −0.560
	After ETO and thermal exposure	0.54/0.0010	7410	22.9	1.1	1.07	1.0	5.2 × 10^14	3390	−4.559	−0.040
		0.54/0.0010	5930	34.3	1.1	1.22	1.0	5.4 × 10^14	3360	−4.745	−0.041
		0.54/0.0010	7040	—	1.1	1.10	1.0	5.4 × 10^14	3280	−4.405	
		0.54/0.0010	7960	—	1.1	1.25					
		0.54/0.0009	8640	21.4							
			(av) 7400	(av) 26.2		(av) 1.16		(av) 5.3 × 10^14	(av) 3340	(av) −4.570	(av) −0.040
Fibremat I 2539	Control	0.496/0.005	2250	109	6	0.60	5.9	3.2 × 10^15	88		
		0.496/0.006	2140	120	5	0.75	5.4	3.1 × 10^15	70		
		0.496/0.006	2300	106	5	0.74	5.9	4.6 × 10^15	69		
					5	0.78					
			(av) 2230	(av) 111		(av) 0.72		(av) 3.6 × 10^15	(av) 76		
	After ETO exposure	0.500/0.0056	2290	86	5	0.80	5.7	5.0 × 10^15	74	0	+5.187
		0.500/0.0053	2350	85	5	0.75	5.8	2.0 × 10^15	53	0	+5.414
		0.500/0.0058	1970	90	6	0.68	5.6	1.9 × 10^15	55	0	+4.300
					5	0.68					
			(av) 2203	(av) 87		(av) 0.73		(av) 3.0 × 10^15	(av) 61	(av) 0	(av) +4.967
	After ETO and thermal exposure	0.488/0.0054	2810	51	6	0.65	5.8	4.8 × 10^16	91	−1.780	+0.094
		0.490/0.0051	2580	51	6	0.62	5.6	2.5 × 10^16	71	−1.064	+0.210
		0.492/0.0055	2590	49	5	0.60	4.8	1.3 × 10^16	66	−1.660	+0.127
					5	0.60					
			(av) 2660	(av) 50		(av) 0.62		(av) 2.9 × 10^16	(av) 76	(av) −1.501	(av) +0.144

Table A-6. Complete test results for ETO decontamination and dry heat sterilization on reinforced PLASTICS

Commercial designation	Exposure conditions	Mechanical properties					Electrical properties			Physical and thermal properties	
		Hardness, Rockwell or Shore	Stressed dimensions, in.	Tensile strength, psi	Elongation, %	Creep	Thickness, mil	Volume resistivity, Ω–cm	Dielectric strength, V/mil	Volume change, %	Weight change, %
Delrin 507	Control	74.7D	0.069/0.497	10,500	23		69.3	1.99×10^{15}	578		
		74 D	0.070/0.494	11,200	12.7		69.7	1.93×10^{15}	438		
		75 D	0.072/0.496	9,800	16.4		70.0	1.70×10^{15}	>643		
		(av) 74.6D		(av) 10,500	(av) 17.4			(av) 1.87×10^{15}	(av) >553		
	After ETO exposure	79.3D	0.069/0.497	4,230	23		71.0	1.05×10^{15}	640	0	+1.447
		79.3D	0.069/0.494	4,220	24		69.4	1.00×10^{15}	562	0	+1.627
		77.3D	0.070/0.496	4,150	14		69.7	1.03×10^{15}	>702	0	+1.775
		(av) 78.6D		(av) 4,200	(av) 20			(av) 1.03×10^{15}	(av) >635	(av) 0	(av) +1.616
	After ETO and thermal exposure	82.3D	0.070/0.489	4,150	22	Failed	68.5	3.3×10^{15}	665	−2.74	−0.886
		82.3D	0.070/0.493	4,170	28		71.2	3.4×10^{15}	673	−1.37	−0.846
		82.3D	0.070/0.493	4,290	25		71.0	3.1×10^{15}	>675	−1.41	−0.865
		(av) 82.3D		(av) 4,200	(av) 25			(av) 3.3×10^{15}	(av) 671	(av) −1.84	(av) −0.866
Fiberglas 91 LD	Control	B77.5	0.131/0.495	33,200	2.8		127.5	9.9×10^{13}	169		
		B81.2	0.130/0.496	33,000	2.2		122.5	2.48×10^{14}	196		
		B79.7	0.133/0.493	35,800	1.9		122.5	2.36×10^{14}	192		
		(av) B79.5		(av) 34,000	(av) 2.3			(av) 1.94×10^{14}	(av) 186		
	After ETO exposure	B80.6	0.129/0.500	34,900	1.96		127.2	4.22×10^{12}	204	+0.244	+0.155
		B82.1	0.129/0.500	35,300	2.04		126.8	9.60×10^{11}	205	+0.238	+0.023
		B81.3	0.128/0.496	36,500	2.04		120.5	8.04×10^{13}	199	0	
		(av) B81.3		(av) 35,600	(av) 2.01			(av) 4.4×10^{13}	(av) 203	(av) +0.161	(av) +0.089
	After ETO and thermal exposure	B87.5	0.129/0.497	33,400		<1% after 552 h at 135°C in a nitrogen atmosphere	128.7	9.6×10^{13}	330	0	−1.560
		B87.2	0.127/0.494	33,500	2.0		131.0	5.1×10^{13}	>267	−0.097	−1.613
		B87	0.125/0.490	34,100	2.0		132.0	6.9×10^{13}	>250	−0.260	−1.562
		(av) B87.2		(av) 33,700	(av) 2.0			(av) 7.2×10^{13}	(av) >262	(av) −0.119	(av) −1.578
Mica Type EG 899, NEMA G-10	Control	R21	0.034/0.498	27,500	3.4		34.3	3.4×10^{15}	817		
		R21	0.034/0.496	29,200	2.1		33.4	3.5×10^{15}	764		
		R20.5	0.034/0.498	29,800	2.6		34.4	2.7×10^{15}	625		
		R21.5	0.034/0.495	26,400	1.6						
		R22	0.034/0.495	29,000	1.8						
		R21									
		(av) R21		(av) 28,400	(av) 2.3			(av) 3.2×10^{15}	(av) 735		

Table A-6 (contd)

Commercial designation	Exposure conditions	Mechanical properties: Hardness, Rockwell or Shore	Stressed dimensions, in.	Tensile strength, psi	Elongation, %	Creep	Electrical properties: Thickness, mil	Volume resistivity, Ω–cm	Dielectric strength, V/mil	Physical and thermal properties: Volume change, %	Weight change, %
	After ETO exposure	R20	0.035/0.497	29,000	2.3		33.8	2.2×10^{15}	903	−0.040	−0.074
		R22	0.035/0.495	29,300	2.0		33.7	2.8×10^{15}	628	−0.040	−0.083
		R22	0.034/0.496	24,400	1.6		33.4	$3 2 \times 10^{15}$	615	0	−0.066
		R21.5	0 034/0.498	29,800	1.9						−0.071
		R21.5	0.034/0.497	27,800	1.7						−0.070
		R21									−0.070
		(av) R21.3		(av) 28,100	(av) 1.9			(av) 2.7×10^{15}	(av) 715	(av) −0.026	(av) −0.072
	After ETO and thermal exposure	R21.5	0.034/0.499	29,100	2.5		33.7	2.8×10^{15}	772	0	−0 366
		R21.5	0.034/0.498	31,300	2.6		34.1	3.3×10^{15}	616	0	−0.407
		R22	0.035/0 498	28,700	2.5		34.1	4.4×10^{15}	587	0	−0 397
			0.034/0.498	26,500	2.2						
			0 034/0 496	28,100	2.6						
		(av) R21.6		(av) 28,700	(av) 2.5			(av) 3.5×10^{15}	(av) 658	(av) 0	(av) −0.390
Zytel 38	Control	68.7D	0.071/0.499	6,830	28.8		70.0	4.4×10^{14}	435		
		68 0D	0.071/0 436	6,940	29.5		68.0	5.0×10^{14}	442		
		66.3D	0.071/0 499	6,770	49.5		70.5	6.1×10^{14}			
		(av) 67.7D		(av) 6,850	(av) 35.9			(av) 5.2×10^{14}	(av) 439		
	After ETO exposure	71 3D	0 070/0 496	2,880	36		68.2	3.8×10^{14}	514	0	+1.695
		72 D	0.071/0.494	2,910	37		70.0	3.9×10^{14}	379	0	+2.311
		72 D	0.070/0.471	2,790	36		67.8	3.1×10^{14}	413	0	+2.039
		(av) 71.8D		(av) 2,860	(av) 36			(av) 3.6×10^{14}	(av) 435	(av) 0	(av) +2.015
	After ETO and thermal exposure	79 D	0.070/0.478	3,700	31	Failed	69.0	6.5×10^{15}	435	−1.39	−0.900
		79.3D	0.071/0 496	3,690	21		68.5	6.8×10^{15}	402	−1.41	−0.896
		80 D	0.072/0.494	3,710	23		67.6	5.6×10^{15}	436	−1.41	−0.910
		(av) 79.4D		(av) 3,700	(av) 25			(av) $6 3 \times 10^{15}$	(av) 424	(av) −1.40	(av) −0.902

Table A-7. Complete test results for ETO decontamination and dry heat sterilization on FOAMS

Commercial designation	Exposure conditions	Mechanical properties					Electrical properties			Physical and thermal properties	
		Tensile strength and elongation			Compression load deflection						
		Stressed dimensions, in.	Tensile strength, psi	Elongation, %	Stressed dimensions, in.	Load to produce 25% compression, psia	Thickness, mil	Volume resistivity, Ω–cm	Dielectric strength, V/mil	Volume change, %	Weight change, %
Eccofoam FS	Control	0.36/0.41	56.4	377	2.024/2.055	0.72	500	4.0×10^{11}	35.5		
		0.43/0.41	45.6	309	1.975/2.006	0.75	500	3.9×10^{11}	33.0		
		0.37/0.40	48.5	307			500	4.3×10^{11}	35.0		
			(av) 50.2	(av) 331		(av) 0.74		(av) 4.1×10^{11}	(av) 34.5		
	After ETO exposure	0 42/0.46	34.9	297	2.017/2.017	0.89	510	2.0×10^{11}	24 0	+4.118	+2.950
		0.47/0.47	36.2	320	2.000/2.088	0.75	505	2.4×10^{11}	34.0	+5.299	+3.594
		0.48/0.46	32.8	280			505	2.5×10^{11}	25.0	+5.662	+3.386
			(av) 34.6	(av) 299		(av) 0.82		(av) 2.3×10^{11}	(av) 27.7	(av) +5.026	(av) +3.310
	After ETO and thermal exposure	0.45/0.50	28	207	2.024/2.012	1.3	500	1.57×10^{13}	26.5	−1.501	−4.604
		0.42/0.35	35	176	2.010/1.997	1.4	500	8.10×10^{12}	36.0	−0.842	−4.159
		0.46/0.47	27	197			500	1.01×10^{13}	34.0	−1.012	−5.055
			(av) 30	(av) 193		(av) 1.4		(av) 1.13×10^{13}	(av) 32.2	(av) −1.118	(av) −4.606
Eccofoam SH	Control	0.996 (diam)	126	67.3	2.001/1.978	171	520	3.5×10^{15}	38.0		
		0.978 (diam)	129	103	2.001/1.975	166	515	4.1×10^{15}	40.0		
		0.998 (diam)	126	57			505	4.0×10^{15}	42.0		
			(av) 127	(av) 76		(av) 169		(av) 3.9×10^{15}	(av) 40.0		
	After ETO exposure	0.996 (diam)	133	71	2.006/2.003	140	517	2.5×10^{15}	45.0	+0.254	+0.558
		0.993 (diam)	128	53	1.995/2.000	170	530	2.6×10^{15}	44.0	+0.712	+0.108
		0.996 (diam)	131	57			513	3.0×10^{15}	47.0	+0.293	
			(av) 131	(av) 60		(av) 155		(av) 2.7×10^{15}	(av) 45.3	(av) +0.420	(av) +0.333
	After ETO and thermal exposure	0.984 (diam)	131	61	1.995/1.990	159	522	3.1×10^{15}	48.0	−1.146	−1.639
		0.993 (diam)	134	61	1.960/1.989	188	518	2.7×10^{15}	51.0	−1.691	−1.977
		0.991 (diam)	139	65			508	2.3×10^{15}	47.0	−1.799	−1.734
			(av) 135	(av) 62		(av) 174		(av) 2.7×10^{15}	(av) 48.7	(av) −1.545	(av) −1.783

Table A-8. Complete test results for ETO decontamination and dry heat sterilization on TAPES

Commercial designation	Exposure conditions	Mechanical properties				Electrical properties			Physical and thermal properties	
		Adhesion, oz/in. width (5-in. av. length separation)	Stressed dimensions, in.	Breaking strength, lb/in.	Elongation, %	Thickness, mil	Volume resistivity, Ω–cm	Dielectric strength, V/mil	Volume change, %	Weight change, %
Mystik 7452	Control	118.1	3	30	10	2.1	8.1×10^{14}	738		
		113.9	3	31	9	2.1	7.0×10^{11}	720		
		100.8	3	28	10	2.1	9.1×10^{14}	643		
		103.0								
		103.0								
		(av) 107.8		(av) 30	(av) 9.7		(av) 8.1×10^{14}	(av) 700		
	After ETO exposure	119.0	3	30	13	2.1	5.1×10^{14}	538	0	+0.144
		113.0	3	33	13	2.1	1.1×10^{14}	595	0	+0.143
		125.1	3	32	14	2.1	3.1×10^{14}	600	0	+0.123
		120.6								
		105.6								
		(av) 116.7		(av) 31	(av) 13.7		(av) 3.1×10^{14}	(av) 578	(av) 0	(av) +0.137
	After ETO and thermal exposure	167.0	3	33	15	2.1	1.49×10^{14}	830	0.751	−0.478
		169.2	3	31	12	2.1	1.09×10^{14}	875	1.257	−0.418
		183.0	3	32	12	2.1	1.38×10^{14}	870		
		136.9								
		152.3								
		(av) 161.6		(av) 32	(av) 13		(av) 1.32×10^{14}	(av) 858	(av) −1.004	(av) −0.448

Appendix B

Complete Data on ETO and Dry Heat Sterilization at 120° and 150°C for Selected Products

Table B-1. Complete test data for Butyl 318-7

Commercial designation	Exposure conditions	Mechanical properties										Physical and thermal properties	
			Tensile bars			Rings			Compression set				
		Hardness, Shore A	Stressed dimensions, in.	Tensile strength, psi	Elongation, %	Stressed dimensions, in.	Tensile strength, psi	Elongation, %	t_0	t_1	% Compression set, $\frac{t_0 - t_1}{t_0 - t_s} \times 100$	Volume change, %	Weight change, %
Butyl 318-7	Control	74.7	0.140/0.480	1620	300	0 126/0 072	1650	280	—	—	—		
		76	0.136/0.480	1640	300	0.124/0.072	1820	310					
		76.2	0.141/0.480	1600	300	0.127/0.070	1560	260					
		76				0.121/0.071	1800	250					
		76											
		74.2											
		(av) 75.5		(av) 1620	(av) 300		(av) 1710	(av) 275					
	After ETO exposure	69.7	0.482/0.139	1700	300	0.131/0.075	1500	310	—	—	—	0	+0.936
		69	0.483/0.140	1510	300	0.129/0.076	1500	330				+0.030	+0.973
		69.2	0.483/0.140	1580	350	0.129/0.076	1480	330					+0.873
		69.7				0.133/0.076	1520	360					
		69 3											
		69.3											
		(av) 69.4		(av) 1600	(av) 317		(av) 1500	(av) 333				(av) +0.030	(av) +0.927
	After ETO and thermal exposure at 150°C	61.3	0.122/0.474	865	370	0.122/0.069	1500	270	0.504	0.394	85.9	−2.010	−2.324
		65	0.124/0.480	1060	350	0.121/0.067	1520	260	0.520	0.398	84.7	−2.643	−2.148
		65.3	0 123/0.479	1120	330	0.121/0.067	1550	265	0.500	0.393	86.2	−2.490	−2.020
									0 5175	0.396	85.8		
		(av) 63.9		(av) 1020	(av) 350		(av) 1520	(av) 265			(av) 85.7	(av) −2.381	(av) −2.164
	After ETO and thermal exposure at 120°C	74	0.124/0.476	1880	240	0.122/0.068	1780	320	0.516	0.396	85.7	−1.879	−1.636
		73.3	0.122/0.477	1800	250	0.124/0 069	1710	320	0.514	0 395	86 2	−1.408	−1.865
		73	0.125/0.480	1630	280	0.123/0.068	1820	330	0.537	0.400	85.0	−2.320	−1.640
									0.549	0.401	85.5		
		(av) 73.3		(av) 1770	(av) 257		(av) 1770	(av) 323			(av) 85.6	(av) −1.869	(av) −1.714

Table B-2. Complete test data for RTV-30/T-12 and Solithane 1/T-12

Commercial designation	Exposure conditions	Mechanical properties					Electrical properties			Physical and thermal properties	
		Hardness, Shore A	Stressed dimensions, in.	Tensile strength, psi	Elongation, %	Peel strength, lb/in. of width	Thickness, mil	Volume resistivity, Ω–cm	Dielectric strength, V/mil	Volume change, %	Weight change, %
RTV-30/ T-12	Control	55.8	0.100/0.473	579	120	2.6	98.5	4.42×10^{14}	476		
		57	0.098/0.475	546	110	3.0	97.6	4.22×10^{14}	488		
		58.2	0.099/0.477	591	120	2.7	97.3	3.87×10^{14}	494		
		57.8				2.9					
		57.5				2.7					
		57.7									
		(av) 57.3		(av) 572	(av) 117	(av) 2.8		(av) 4.17×10^{14}	(av) 486		
	After ETO exposure	58.5	0.099/0.477	424	80	3.0	98.8	2.65×10^{14}	>486	+0.406	+0.149
		57.6	0.100/0.476	506	110	3.1	97.7	2.16×10^{14}	492	+0.104	+0.195
		58.5	0.101/0.476	497	100	3.3	97.7	2.30×10^{14}	492	+0.208	+0.385
		57.7				3.1				+0.801	+0.275
		58.2				2.7				+0.793	+0.322
		57.7								+1.427	+0.309
		(av) 58.1		(av) 476	(av) 97	(av) 3.0		(av) 2.37×10^{14}	(av) >490	(av) +0.623	(av) +0.273
	After ETO and thermal exposure at 150°C	60	0.100/0.475	421	81		102.5	1.04×10^{15}	396	−0.353	−0.436
		61	0.100/0.475	556	100		98.0	1.03×10^{15}	470	−0.177	−0.450
		61	0.101/0.479	525	100		100.0	1.04×10^{15}	>480		−0.450
		(av) 60.7		(av) 501	(av) 94			(av) 1.04×10^{15}	(av) >449	(av) −0.265	(av) −0.445
	After ETO and thermal exposure at 120°C	63 8	0.100/0.476	546	110		102	3.7×10^{14}	421	−0.808	−0.352
		63	0.102/0.475	557	110		102	$3\ 3 \times 10^{14}$	>471	−1.115	−0.363
		62.8	0.102/0.474	538	100		101	4.0×10^{14}	475	−0.813	−0.355
		(av) 63.2		(av) 547	(av) 107			(av) 3.7×10^{14}	(av) >456	(av) −0.912	(av) −0.357

Table B-2 (contd)

Commercial designation	Exposure conditions	Mechanical properties: Hardness, Shore A	Mechanical properties: Stressed dimensions, in.	Mechanical properties: Tensile strength, psi	Mechanical properties: Elongation, %	Mechanical properties: Peel strength, lb/in. of width	Electrical properties: Thickness, mil	Electrical properties: Volume resistivity, Ω–cm	Electrical properties: Dielectric strength, V/mil	Physical and thermal properties: Volume change, %	Physical and thermal properties: Weight change, %
Solithane 1/T-12	Control	59.3	0.099/0.478	412	90	0.64	103.5	8.0×10^{14}	>464		
		58.2	0.100/0.482	405	90	1.35	104.0	8.4×10^{14}	>462		
		58.7				0.74	102.5	7.9×10^{14}	>469		
		58.5				0.94					
		59.2				0.97					
		59.2									
		(av) 58.9		(av) 408	(av) 90	(av) 0.93		(av) 8.1×10^{14}	(av) >465		
	After ETO exposure	64.8	0.105/0.478	408	90	0.42	97.2	1.43×10^{14}	>494	+1.621	+1.242
		65.3	0.105/0.483	375	90	0.40	96.5	1.10×10^{14}	431	+0.504	+1.233
		64.5	0.104/0.481	440	100	0.46	103.5	1.42×10^{14}	368	+1.004	+1.297
		63				0.74				+1.740	+1.282
		63 7				0.39				+0.911	+1.228
		63.7								+1.736	+1.263
		(av) 64.2		(av) 408	(av) 93	(av) 0.48		(av) 1.32×10^{14}	(av) >431	(av) +1 253	(av) +1.258
	After ETO and thermal exposure at 150°C	44.3	0 099/0 470	161	120		101.0	3.3×10^{13}	327	Samples deformed	−0.991
		37.7	0.103/0.475	196	140		100.0	2.1×10^{13}	>480		−1.895
		35	0 097/0.478	112	110		99.0	1.2×10^{13}	475		−2.391
		(av) 39		(av) 156	(av) 123			(av) 2.2×10^{13}	(av) >427		(av) −1.759
	After ETO and thermal exposure at 120°C	58.8	0.102/0.480	296	110		100.5	1.76×10^{14}	>477	−0.593	−0.392
		59	0.102/0.475	246	100		99.5	2.94×10^{14}	>483	−0.902	−0.452
		60	0 101/0.477	286	110		100.0	2.19×10^{14}	>480	−0.602	−0.297
		(av) 59 3		(av) 277	(av) 107			(av) 2.3×10^{14}	(av) >480	(av) −0.699	(av) −0.380

Table B-3. Complete test data for Kapton 100-XH-667

Commercial designation	Exposure conditions	Mechanical properties					Electrical properties			Physical and thermal properties	
		Tensile strength and elongation			Tear strength						
		Stressed dimensions, in.	Tensile strength, psi	Elongation, %	Thickness, mil	Tear strength, lb/mil	Thickness, mil	Volume resistivity, Ω–cm	Dielectric strength, V/mil	Volume change, %	Weight change, %
Kapton 100-XH-667	Control	0.49/0.0009	22,300	21	1.1	2.59	1.3	8.6×10^{16}	4580		
		0.49/0.0009	22,600	33	1.1	2.28	1.4	1.31×10^{17}	4640		
		0.49/0.0009	20,700	31			1.3	1.18×10^{17}	4670		
			(av) 21,900	(av) 28		(av) 2.43		(av) 1.12×10^{17}	(av) 4630		
	After ETO exposure	0.50/0.0012	11,600	10	1.2	0.46	1.2	8.4×10^{16}	5100	+0.101	+1.993
		0.50/0.0013	10,800	10	1.1	0.69	1.1	5.5×10^{16}	5740	+0.299	+2.466
		0.49/0.0012	12,100	10	1.2	0.60	1.1	5.4×10^{16}	5780	+0.201	+0.519
										+0.125	+2.021
										0	+1.794
										+0.302	+2.065
			(av) 11,500	(av) 10		(av) 0.58		(av) 6.4×10^{16}	(av) 5540	(av) +0.172	(av) +1.810
	After ETO and thermal exposure at 150°C	0.49/0.0009	20,200	23	1.1	2.31	1.2	6.2×10^{16}	5240	−0.600	−0.131
		0.49/0.0009	19,000	28	1.1	1.67	1.2	6.3×10^{16}	5250	−0.805	
		0.49/0.0009	22,700	28			1.2	8.1×10^{16}	4720	−0.302	
			(av) 20,600	(av) 26		(av) 1.99		(av) 6.9×10^{16}	(av) 5070	(av) −0.569	(av) −0.131
	After ETO and thermal exposure at 120°C	0.48/0.0011	22,000	20	1.1	1.5	1.1	1.02×10^{17}	5850	0	0
		0.48/0.0011	23,500	30	1.1	1.5	1.1	1.15×10^{17}	5630	0	−1.125
		0.49/0.0011	20,400				1.1	9.30×10^{16}	5670	−0.150	+0.649
			(av) 22,000	(av) 25		(av) 1.5		(av) 1.03×10^{17}	(av) 5720	(av) −0.050	(av) −0.159

Table B-4. Complete test data for Fiberglas 91 LD

Commercial designation	Exposure conditions	Mechanical properties: Hardness, Rockwell B	Mechanical properties: Stressed dimensions, in.	Mechanical properties: Tensile strength, psi	Mechanical properties: Elongation, %	Electrical properties: Thickness, mil	Electrical properties: Volume resistivity, Ω–cm	Electrical properties: Dielectric strength, V/mil	Physical and thermal properties: Volume change, %	Physical and thermal properties: Weight change, %
Fiberglas 91 LD	Control	78 8	0.495/0.131	33,200	2 8	127.5	9.9×10^{13}	169		
		82.5	0.496/0 130	33,000	2.24	122.5	2.48×10^{14}	196		
		80.5	0.493/0.133	35,800	1.92	122.5	2.36×10^{14}	192		
		(av) 80.6		(av) 34,000	(av) 2.32		(av) 1.94×10^{14}	(av) 186		
	After ETO exposure	80.7	0.500/0.129	34,900	1.96	127.2	4.22×10^{13}	204	+0.244	+0.155
		82.8	0.500/0.129	35,300	2.04	126.8	9.6×10^{11}	205	+0.238	+0.023
		80.7	0.496/0.129	36,500	2.04	120 5	$8 04 \times 10^{12}$	199	0	
		79.9								
		82 2								
		84.2								
		(av) 81.8		(av) 35,600	(av) 2.01		(av) 4.4×10^{12}	(av) 203	(av) +0.161	(av) +0.089
	After ETO and thermal exposure at 150°C	84.2	0.488/0.115	30,600	2.14	138	3.2×10^{13}	>348	−1.664	−1.842
		87.3	0.495/0.116	30,900	2.33	127	6.3×10^{13}	348	−2.673	−1.964
		85	0.494/0.116	29,900	1.96	138	4.3×10^{13}	315	−2.255	−1.857
		(av) 85.5		(av) 30,500	(av) 2.14		(av) 4.6×10^{13}	(av) >337	(av) −2.197	(av) −1.888
	After ETO and thermal exposure at 120°C	87	0.490/0.117	34,904	1.8	139	3.4×10^{13}	>345	−1.491	−1.974
		84	0.498/0.115	39,790	1.8	137	4.7×10^{13}	>350	−1.195	−1.913
		87	0.498/0.113	39,800	1.8	139	6.1×10^{13}	>345	−0.893	−1.947
		(av) 86		(av) 38,200	(av) 1.8		(av) 4.7×10^{13}	(av) >347	(av) −1.193	(av) −1.945

Appendix C

Description of Polymeric Products That Required Preparation Before Testing

Table C-1. Preparation of ADHESIVES

Product designation and manufacturer	Material type	Mixing ratio	Pot life at room temperature	Cure time and temperature
4684/RC-805 Du Pont	Two-part, modified synthetic rubber adhesive; 30% solids	100 g 4684 to 5 g RC-805	1 h	½-h warm-up to 300°F under 25 psi; then ½ h at 300°F
46950 Du Pont	One part polyester adhesive; 20% solids	Use from can, thoroughly mixed	—	As above
EC-1614 B/A 3M Co.	Two-part epoxy-based, amine-cured adhesive; 100% solids, tan	1 part A to 1 part B, by weight	¾ h	¼ h at 200°F
EC-2216 B/A 3M Co.	Two-part epoxy-based, amine-cured adhesive; 100% solids, gray	140 parts A to 100 parts B, by weight	2 h	2 h at 150°F
Eccobond 45/15 Emerson and Cuming	Two-part epoxy-based, polyamide-cured adhesive; filled; black	1 part No. 45 to 1 part No 15, by weight	3 h	16 h at 125°F
RTV-40/T-12 General Electric	Two-part silicone-based, dibutyltindilaurate cured adhesive; white	100 g RTV-40 to 0.1 g T-12; apply to primed surface	1 h	24 h at room temperature; then 24 h at 275°F

Table C-2. Preparation of COATINGS

Product designation and manufacturer	Material type	Mixing ratio	Pot life at room temperature	Cure time and temperature
Chemlock 607 Hughson Chemical	Not specified	Use from can, thoroughly mixed	—	24 h at room temperature
SS-4004 General Electric	One part silicone resin-based primer; pink	As above	—	24 h at room temperature
SS-4101 General Electric	One part silicone resin-based primer, clear	As above	—	24 h at room temperature
SS-4044 General Electric	One part silicone resin-based primer; clear	As above	—	24 h at room temperature

Table C-3. Preparation of ENCAPSULANTS

Product designation and manufacturer	Material type	Mixing ratio	Pot life at room temperature	Cure time and temperature
PR-1527 A/B Products Research	Two-part polyurethane system; 100% solids; amber	26 g part A to 100 g part B; mix thoroughly; degas 10 min below 3 mm pressure	½ h	16 h at 160°F
PR-1535 Products Research	Two-part polyurethane system; 100% solids; amber	32 g part A to 100 g part B; proceed as above	½ h	8 h at 180°F
PR-1538 Products Research	Two-part polyurethane system; 100% solids; amber	32 g part A to 100 g part B; proceed as above	½ h	8 h at 180°F
PR-1547 Products Research	Two-part polyurethane system; 100% solids; amber	32 g part A to 100 g part B, proceed as above	½ h	8 h at 180°F
RTV-30/T-12 General Electric	Two-part silicone system; 98% solids; red	100 g RTV-30 and 0.1 g T-12; degas 10 min below 3 mm pressure; apply to primed surface	½ h	24 h at room temperature; then 24 h at 275°F
RTV-3116 (Formerly RTV-881) Dow Chemical	Two-part silicone system; white	100 g RTV-3116 to 2 g 3116 catalyst, and 0.16 g T-12; proceed as above	½ h	24 h at room temperature; then 24 h at 275°F
Solithane 1 Thiokol Chemical	Polyurethane system; light amber	To 100 g Solithane 113 add 73 g of C-113-300 catalyst mixed with 0.36 g T-12; mix thoroughly and degas 10 min below 3 mm pressure	½ h	5 h at 165°F
Solithane 4 Thiokol Chemical	Polyurethane system; light amber	To 100 g Solithane 113 add 100 g of C-113-300 catalyst mixed with 0.36 g T-12; proceed as above	⅓ h	5 h at 165°F
Solithane 12 Thiokol Chemical	Polyurethane system; light amber	To 100 g Solithane 113 add 36.5 g C-113-300 mixed with 7.5 g C-113-328 and 0.08 g T-12; proceed as above	1/6 h	5 h at 165°F