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A STUDY OF
REPORTED CONDOM DETERIORATION

A Report Prepared By:

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CONSULTANT REPORT ON
REPORTED CONDOM DETERIORATION

I. INTRODUCTION - BASIS FOR THE STUDY

This study of complaints of deteriorated condoms (breakage, discoloration or "moldy" appearance) has been undertaken at the request of the AID, Office of Population, Family Planning Services Division to verify the reports from AID recipient programs of unacceptable condoms and if found to be accurate to determine the extent of the problems. Observations regarding the effect of poor condoms on program success have been made. Sources of present or future difficulties were explored. Recommendations have been made to minimize the likelihood of future problems developing. An important aspect of the study has been to visit countries in which complaints have been registered and to review problems with program personnel. Condoms were sampled in in-country warehouses and at the retailer level and tested in the United States in accordance with GSA specifications for mechanical integrity since there have been a number of reports of breakage. Evaluation of product appearance of sampled condoms has also been undertaken as there have been complaints of "moldy" appearance, discoloration and brown spots in the lubricant. A few reports of unpleasant odors in the packaged condoms have also been made and this has also been subjectively evaluated.

The complaints have generally involved Akwell condoms produced under several brand names, but have recently focused

on Tahiti and other colored condoms. Samples of condoms purchased offshore by GSA and Japanese condoms donated by the Japanese government have been sampled and tested for comparison as well as Akwell colored condoms sold in regular commercial channels. Packaging, in-country warehousing, and turnover of stocks as they might affect the condoms were explored.

Recent complaints from the Jamaica, Thailand and Bangladesh CB programs were the areas of particular concern. (CB programs as described in this study refer to programs distributing AID supplied condoms (and pills) through retailers in existing commercial channels or through selected volunteers who are community based and recruited by the program to sell contraceptives at subsidized prices). The administrators of these programs have felt that the programs were vulnerable to consumer criticism, and resistance if defective product were distributed, with the real possibility of program failure.

The reports have originated from the CB programs, primarily. A few government free programs (some in CB condom complaint countries) have reported significant complaints. Several IPPF affiliates (Kenya, St. Kitts) providing free distribution have also complained. Some CB programs (Colombia) distributing Tahiti (Akwell colored condoms) have not reported any complaints.

The Jamaica CB program reported condoms breaking or bursting in use. Thailand and Bangladesh CB programs have reported breaking, moldy and discolored condoms. (It has been conjectured, but not demonstrated, that users who pay for condoms would be more likely to complain if they have trouble).

II. HISTORY OF REPORTS OF DETERIORATED OR DEFECTIVE CONDOMS

The record available to the investigator indicates that complaints concerning defective or deteriorated condoms appear to be directed solely to those brands manufactured by Akwell and purchased by GSA on behalf of AID. The condoms in question were made available to recipients either through bilateral arrangements or by a third party, particularly IPPF.

The only other report of unsatisfactory U.S. supplied condoms was directed at Trojans (Youngs Rubber) for being excessively lubricated which has been attributed to the use of water-base lubricant.

In August, 1975, AID/Dacca reported that Conture brand (date of mfr. 2/75) appeared dirty. Then in November 1975, IPPF reported on condoms shipped to the Thai CBFPS program as showing deterioration to the extent that Conform (dated 7/74 and 3/74) were "mechanically deteriorated," Conture (dated 12/74) were "discolored and perhaps mechanically deteriorated" and Tahiti (dated 4/75) had "lubricant beginning to discolor."

Mr. George Nakamura in January 1976, reported that AID/Dacca also observed that Conture (2/75) and Sultan (1975) appeared to have lubricant problems compared to Sultan Brand received in 1974. The same letter quoted Mr. Lucas Hendratta of the Indonesian CB program as describing Conform quality as being "poor" and had a tendency to tearing in use." (This was confirmed by Mr. Hendratta's personal experience).

After receiving complaints from AID, Akwell conducted their own investigation. In April 1976 Mr. William Henderson, of Akwell, commenting on the Thai difficulties advised that tests on Conture and Conform passed minimums as measured by tensile strength and elongation on breaking and that brown spots in Tahiti lubricant were "slight." Akwell observation and testing of other samples submitted indicated that condom strength was well above minimums, but that there was definite indications of lycopodium powder not absorbed by the silicone. Mr. Henderson noted that some packages received from Indonesia had an "undesirable yellowish tone in the film" which was crystalline and when cleaned in the laboratory was acceptable. Packaging film deterioration was attributed by him to "environmental factors."

Tests on Tahiti from Bangladesh performed at Wilro Science Laboratories, an Akwell sister company, were reported in November 1976 with the conclusion that "a mold of the Penicillium genus was found to be the cause of the discoloration of the film. The odor also appeared to be caused by the fungus." High humidity storage conditions were implicated by the laboratory as necessary to allow mold growth. Discoloration of the lubricant was also noted by Wilro.

At Akwell's request, American Can Company's laboratory examined Tahiti returned from the field and concluded on October 8, 1976 that the packages were stored at extremely high humidity and temperature for a period of time "and it appeared that the cases or cartons may have been stacked high and under considerable pressure." (Subsequent observations by this investigator were to confirm the hypothesis).

They also noted a musty smell when the packages were opened. Although no defect was observed in the polyethylene, they advised that polyethylene will soften under high heat and humidity and that "under these conditions the poly apparently pulled away from the cellophane in spots." Moldy appearance inside the package was attributed to adverse environmental factors. American Can concluded that a foil combination was indicated in view of the conditions to which the package was subjected.

Mr. Henderson visited Thailand and Bangladesh in late 1976 and concurred in the poor condition of part of the stock of Conture/Conform in Thailand and, without prejudice, agreed to replace that portion with the proviso that the bad condoms be scrapped.

Akwell has generally taken the position that the condoms that they supply pass the same tests that they use for all their production including their commercial sales both in the United States and overseas. They observe that the condoms also meet the GSA specification which, in addition to water leakage tests for pinholes, included at one time air burst tests (and now requires tensile tests) before and after accelerated aging of the condoms in their package. They point out that since Tahiti is one of their established brands, it is in their interest to protect the quality image. Akwell has also advised that their brands are shipped into Great Britain, Canada, and Sweden and are tested routinely by regulatory bodies in these countries.

Akwell has stated the shelf life of their condoms should be five years, but make this conditioned on proper storage, which is not defined. In January 1975, Mr. George Decker of the National Bureau of Standards conducted a study of aging characteristics of rubber condoms at the request of Mr. Theodore Markow of FPSD/POP/PHA. The condoms tested were of Akwell manufacture. He concluded that the condoms "will last for several years if stored at room temperature, in hermetically sealed packages, and in the absence of sunlight." Mr. Decker estimated approximate shelf life against storage temperature (herein reproduced).

<u>Storage Temperature</u> <u>oC</u>	<u>Approx. Shelf Life</u> <u>Years</u>
23	20
30	13
35	8
40	5
45	3
50	1.5

(Mr. Decker's tests were performed without subjecting the packaged condoms to humidity or mechanical load).

III. SPECIFICATIONS

A. GSA's Interim Federal Specification ZZ-C-001597 (GSA-FSS) dated February 10, 1970 for Condom, Rubber Contraceptive has been the document to which AID/GSA purchases have been made during the period in which the condoms in doubt have been provided by Akwell. The specification requirements include:

- 1) Material
- 2) Dimensions
- 3) Construction
- 4) Weight
- 5) Bursting strength - The condoms shall break at a minimum of 1.0 cubic foot volume with air inflated to burst before and after accelerated aging.
- 6) Pinholes - No evidence of pinholes when tested individually electronically.
- 7) Water leakage - A test for "durability" conducted on a sampling basis after pinhole testing and prior to shipment.
- 8) Lubricant - Conforming to manufacturer's current commercial practice. Any material applied to the condom (lubricated) shall not have a deleterious effect on the condom or have a harmful or irritating effect on the body.
- 9) Identification marking
- 10) Workmanship - The workmanship shall be first class. The condoms shall be free from defects which effect their durability, detract from their appearance or which may impair their serviceability.

In addition, the specification places responsibility for inspection on the supplier.

Sampling for the water leakage test are matched to Military Standards MIL-STD-105. Also, the "normal, tightened or reduced inspection provisions of MIL-STD-105 may be used, as applicable, as sampling plans in this specification."

Methods of testing are also described.

Both packaging and packing shall be in accordance with the suppliers standard commercial practice.

B. GSA revised the Interim Federal Specification for Condoms on September 19, 1977 to ZZ-C-001597A (GSA-FSS) which would be used in future purchases.

The principle changes to the earlier specifications are:

- 1) The classification according to type, style, class and sizes have been elaborated.
- 2) The amount of lubricant either water base type or silicone oil type has been specified between minimums and maximums.
- 3) The air burst test has been dropped and in its place a tensile strength test and elongation at break described in Section 6 of ASTM D3492 (American Society of Testing Materials is substituted.) The ASTM specification is appended to this report.
- 4) Packaging of individual condoms in strips as now described and provision for transparent plastic film to facilitate identifying colored condoms.

C. Other Specifications

Of specific interest is the ASTM specification D3492 and the MIL-STD-105 for Sampling Procedures and Tables for Inspection by attributes.

In addition there is a working group under the sponsorship of the International Standards Organization which is trying to develop international standards. Among the countries represented are the United States, Japan, the United Kingdom, Sweden, Denmark, France, India and the Netherlands.

IV. POSSIBLE SOURCES OF DIFFICULTIES FOR
· CONDOMS UNDER INVESTIGATION

A. BREAKAGE

1. Improper manufacture in latex formulation, the dipping process and curing.
2. Improper testing
3. The package material permits air to pump in and out
4. The packaging seals not complete or fail
5. Some colors might predominate
6. Powder and silicone under adverse storage conditions and poor packaging may affect the latex.

B. DISCOLORATION

1. Poor color additive
2. Under adverse conditions powder and lubricant may affect color
3. Brown spots caused by affect of package sealing heat on powder or lubricant

C. CLUMPING OF POWDER IN LUBRICANT

1. Too much powder is used in finishing
2. Too much silicone may encourage occluding of the powder
3. The package material or seal permits moisture into package.
4. The degree of clumping may be time and heat related
5. Shape of condom may increase wrinkles in rolled condom making clumping more apparent..

V. OBSERVATIONS

A. GENERAL OBSERVATIONS

1. CB Programs (and condom usage) are strongly identified with brand names. Tahiti condoms have generally been used in 3 unit cartons with the new brand name on the outside.

(a) Jamaica - The CB program is closely identified with "Panther" in substantial print, billboard and radio advertising.

(b) Thailand - The CBFPS program promotes "Rainbow" through aggressive publicity rather than advertising. The publicity gives significant public exposure to CBFPS. Condoms are called "Mechais" after the CBFPS Director. There are several commercial competing brands.

(c) Bangladesh - The PSI program is strongly promoted in print media and a heavy point of purchase display campaign with Raja brand. There are few competing brands, commercially but there is an extensive government free condom program.

2. Income generated from condom sales are important to program viability.

(a) Thailand - A significant contribution to income would be jeopardized if consumers deserted CBFPS Rainbow condoms. Sales, which are mostly in Bangkok, are vulnerable to adverse rumors.

(b) Bangladesh - Condom sales revenues cover about 20% of program costs.

3. CB pill brands are closely identified with condom brands and their sales may experience adverse reaction from publicity about bad condoms.

- (a) Jamaica - "Perle" associated with Panther brand
- (b) Bangladesh - "Maya" with Raja

4. Having several brands (or product from other manufacturers) may provide a fallback position if product which is associated with given brand becomes deteriorated or gets a poor public reputation.

(a) Thailand - CBFPS found it necessary to create Rainbow "Special" using Japanese condoms. This may have another purpose, however, to create another brand to compete in the market at a different price level.

(b) Bangladesh - The PSI advertising agency BITOPI consumer/retailer survey shows concern about Tahiti breakage. The introduction of Raja brand condom packages as a substitute for Tahiti in the 3 condom pack may deflect criticism: However, Tahiti are soon to be distributed in the government program hopefully without being touched by the poor image from the Raja program.

5. Akwell lot numbers on shipping cases and 100/144 piece cartons cover a number of batches relating to different color runs on the dipping line. A manufacturing deficiency relating to one color would require exploring Akwell's cross referencing. Whereas batch numbers within a lot may vary, the lot number is indicative of a group of condoms that have undergone the same packaging and lubricating. It is difficult to ascertain whether the amount of powder is batch (color) related or lot related.

6. Condoms may be stored in tropical countries too long under adverse conditions. If they become defective, costs for scrapping may override costs if the product was stored longer in temperate climate and smaller more frequent shipments were arranged. It may be economically advisable to invest in basically satisfactory storage facilities in the tropical country.

7. Nirodh (India) or Preethi (Sri Lanka) CB programs which distribute natural color latex condoms in aluminum foil have not reported significant complaints although they both serve markets in humid tropical areas. The packaging, however, is aluminum foil, not polyethylene/cellophane.

8. CB program retailer and distributor stocks are almost always out of direct sunlight. Turnover of stock is usually within several months and more often within a month at the retail level. The Jamaican distributor whose stocks are 2 years old has provided an air conditioned warehouse and a number of the drug stores are air conditioned. In Thailand and Bangladesh CB programs air conditioning is almost non-existent at the retail level but even the smallest stall is shaded.

B. PACKAGING AND BOXING

1. Tahiti, Conture and Conform (Akwel brands) have exhibited occluded powder, discoloration and some degree of breakage after some time in tropical conditions. These brands are packaged in plastic (polyethylene/cellophane) - one side being clear (see Akwell's film specification). Other brands both programmatic and commercial, packed in aluminum foil laminate or a heavier plastic or laminate appear to fare better without a reportable incidence of the above problems.

(a) Durex - Gossamer and Fetherlite which has foil on both sides is used in the IPPF Preethi program in Sri Lanka. Fiesta (color) has foil on one side with a clear window and is sold through regular commercial outlets.

(b) Fuji - Color condoms packaged with foil on one side are distributed in the Thai government program.

(c) Various Japanese condoms that AID provided to the Thai program have color foil on one side.

(d) Schmid natural condoms packaged with foil on one side and having with a 1973 manufacture date on the condom were observed in Bangladesh.

2. The Akwell 100 or 144 piece paperboard box does not seem to be rigid enough either in composition or box configuration to sufficiently protect against mechanical movement or perhaps mechanical loading of stored improperly for long periods in the tropics.

(a) Whether in either the 80 gross and 40 gross shipping case, the Akwell paper box appeared squashed upon observation in the warehouses in the countries visited.

(b) Japanese condoms in the Thai government program were packed in more cubelike, stiffer paperboard boxes which seem to provide greater protection.

3. The Akwell 40 gross shipper with banding in one direction was significantly in better condition than the 80 gross case. The 80 gross case was often damaged because it was small enough for one man to barely lift but too large to carry easily and was often bounced or dropped.

(a) Jamaica and Thai - The CB program 80 gross cases with Tahiti showed a fair amount of damage.

(b) Bangladesh - The 40 gross shipping case looked in satisfactory condition.

(c) Japanese condoms were packed in wooden crates or in 40 gross cases of very heavy cardboard with banding in two directions.

4. Japanese condoms were supplied in 144 piece cartons in a sealed polyethylene bag within the paperboard box. This provides an additional protection layer against vapor or air transmission.

5. Condoms are sold or distributed in loose strips or paperboard packages depending on whether the provider is a government or CB program. Sometimes the condoms are sold by the piece to customers by retailers. Loose condoms may be adversely affected if exposed to ultra-violet light through the clear window in the form of sunlight or fluorescent light.

(a) Jamaica - The CB program sells three Panther (Tahiti) in a paperboard carton from a wall or popup counter display box. The NFPB clinics distribute Tahiti condoms free in strips of three. There are no field workers in this program.

(b) Thailand - The CBFPS program sells Tahiti condoms in a carton containing three pieces through drugstores, quack doctors and rural retailers. Some rural retailers sell them in loose strips at a lower price. The government condoms are distributed free in clinics, but have

been primarily Japanese condoms in loose strips which have been either U.S. purchased or Japanese government donated.

(c) Bangladesh - The PSI program condoms are mostly bought in packages of three but are also sold individually by the piece from the carton. Government field workers and clinics give out loose strips of three.

6. The effectiveness of the film used in the Akwell plastic pouch (polyethylene/cellophane), the gauge of the film and the adequacy seal for long term, high temperature and/or high humidity storage has not been clearly determined.

(a) Akwell personnel advised that no tests are performed on packaged condoms to evaluate package integrity either of the film or the quality of the seal produced by the sealing machines.

7. Conture condom samples received in Thailand in 1976 by W. Henderson Akwell's V.P. Operations were tested at their affiliate Willro Laboratories and exhibited vegetative growth which could be indicative of package failure.

8. The clear window to enable the customer to see the variety of colors may be detrimental to condom strength in clinic or other free distribution if that side is exposed to sunlight or fluorescent light for several days. In addition, the clear window provides easy visualization of clumped powder.

C. EXPIRY DATES

1. Expiry dates, or an external record of the manufacturing dates, are not stamped on the retail dispenser or on the condom

package itself so that it is difficult to establish how old the condoms are without unrolling a condom once the product has been repackaged.

(a) In none of the programs could a salesman easily identify old retailer stocks and replace them to avoid breakage complaints from aged condoms.

(b) Several Japanese brands have an expiring date stamped on the condom wrapper.

(c) Durex Fiesta and a Malaysian brand (Sagami) manufacture have an expiry date printed on the three piece carton.

2. There is no method of establishing or informing programs of expiry expectations for condoms. Time for storage distribution and retail sales may be factored into program administrators plans. Local climate conditions and their effects are not factored into Akwell's professed 5 year shelf life. Some programs set their own arbitrary expiry period.

(a) Manufacturers who show an expiry date on either the wrapper or box (see above) seem to use 3 or 4 years.

(b) Thailand - The CBFPS program has marked a 3 year (after manufacture) expiry on the outside of 80 gross cases. Although questioned no one in CBFPS could provide a reason for this determination.

3. There is no mechanism for testing condoms suspected of deterioration whether through regional, bilateral or international agencies.

(a) Condom testing for tensile strength could be performed in materials testing laboratories or in engineering schools.

(b) Testing may be reasonably limited to tensile strength and % elongation at breaking as a primary indicator of rubber deterioration due to aging, exposure to light, mechanical damage or oxidation or of the latex.

D. BREAKAGE

1. Complaints of breakage have originated mostly from CB programs. This may be due to customers, having paid for the condoms, reacting directly than those users who receive them free from government programs. It may also be that CB program officials more sensitive to consumer reactions respond to complaints more readily. Akwell brands seem to be implicated more than others, but they are more widely distributed than any other manufacturers condoms with greater chance for complaints. Some small amount of breakage seems possible from manufacturing defects which escape quality control or due to mishandling by the user.

(a) Breakages were reported in the Jamaican, Thai, and Bangladesh CB programs with Tahiti. Thailand reported difficulties with Conture and Conform over one year ago. This may be attributable to storage conditions and the latex formulation. (See 5 E 8)

(b) The Sri Lanka Preethi CB Program used Durex and has not complained at all to IPPF about breakage.

(c) The Colombia Profamilia CB Programs which have used Tahiti have not experienced any complaints of breakages from users.

2. Several programs which distribute free condoms have complained about breakage with Akwell condoms (Tahiti).

(a) The Kenya Family Planning Association complained to IPPF and sent samples for testing. The results of the test by the investigator (Philip Kestleman) reflect badly on the quality of manufacture of Tahiti condoms shipped to Kenya.

(b) In response to an AID/Dacca cable the AID/Jakarta office advised that the Indonesian government program had problems with Akwell brands breaking.

3. The results of testing are included. The condoms tested were sampled in program warehouses and at the retail level. The results are:

(a) The Jamaica Tahiti condoms easily met ASTM (now GSA) specifications for tensile strength and % elongation required for condoms for a period beyond one year from manufacture. A very few condoms failed in the air burst test at less than the old GSA specification requirement of 1 cubic foot. Those that failed were mostly those that did so at 0.85 cu. ft. or better. One failed with little air.

(b) Thailand CBSPS Tahiti condoms passed the ASTM specification with considerable margin above tensile strength minimums for both the mean of the sample and that allowed for any given specimen.

(c) Bangladesh CB program Tahiti also readily met ASTM requirements for the mean of the sample and any individual pieces and therefore are acceptable.

4. If the possible serious manufacturing defects are discounted as unlikely (however, see Breakage, 2a), breakage could result from aging, exposure to ultraviolet light, heating and exposure to air, or mechanical damage according to DRs.

G. McKenna and J. Stehler of the National Bureau of Standards.

E. OCCLUDED POWDER, DISCOLORATION

1. In several countries clumping of powder in Tahiti condoms which in extreme cases creates a "moldy" look seemed to be significant on observation by the investigator. The countries that have experienced this are tropical and have high humidity.

(a) Thailand - Clumping of the powder appears to be limited to Tahiti (and before that Conture) and may be related to packaging and storage. Akwell's Samoa (the commercial version of Tahiti) showed very little occluded powder. Japanese condoms of similar vintage did not exhibit clumping at all.

(b) Bangladesh - Tahiti manufactured for the CB program in September through November 1976, which were stored in the U.S. until May 1977, and which have been in Dacca from September 1977 are exhibiting an occluded powder problem to varying degrees of severity. Visual inspection prior to repackaging by the CB program has produced a 0.3% rejection rate but this inspection has not been too rigorous.

(c) Bangladesh - Tahiti from the government's Dacca District warehouse showed marked evidence of occlusion and no lubricant. These have gone through a rainy season in Dacca. These condoms were stored, at the local level, under conditions similar to the PSI warehouse.

2. The amount of powder (a dressing applied by Akwell of lycopodium powder or starch to facilitate handling) and lubricant seem to be variable and they are variable in proportion to each other.

(a) Thailand and Bangladesh - Tahiti have white spots on the surface where the powder (starch) is excessive.

(b) Bangladesh - Tahiti, now in country, and Raja of August 1977 manufacture have considerable lubricant and the powder appears almost as a coating.

(c) Thailand - Japanese condoms (Japanese government and U.S. supplied) are less lubricated, have almost no powder (if at all) and no evidence of occlusion.

These have been manufactured as far back as 1974. Durex, purchased in regular retail channels, also has little powder and exhibited no clumping or spotting.

3. Consumer complaints in the programs visited seem to focus on breakage rather than appearance. Concern for appearance seems to be strong with program administrators. Tahiti are repackaged and probably rarely examined by the customer prior to use. Clumping and "moldy" looking may be significant only if severe and if there are enough reports of breakage to cause consumers to look closely at the condoms.

(a) Thailand - The CBFPS program is competing with other brands in part of its program. Comparisons by consumers are easy to make to the detriment of Rainbow/Tahiti. There have been newspaper gossip column reports of poor CBFPS condoms.

(b) Bangladesh - A retailer/consumer survey by the CB program did not implicate appearance as a source of complaint. The free government program provides loose strips where this has not become an issue at all although powder was clumped and spotting. This lack of concern may relate to the fact that few other brands are available in Bangladesh for comparison.

(c) No retailers in either Thailand or Bangladesh complained to the investigator about appearance although a few commented about breakage.

4. Discoloration seems to accompany the "moldy" look. Some of this may be a lightening of color due to the powder, but some discoloration may be due to unknown factors such as the effect of air or moisture on the powder and lubricant with time and heat.

5. The clumping of the powder may be a function of vapor transmission into the package which could also indicate air being pumped in and out.

6. In a few instances, brown spots have appeared in the lubricant starting at the seal. The spots may actually be in the powder and may be related to the heat used in sealing. However, no information regarding the source of this difficulty is available.

7. Akwell acknowledges the use of a heptene based accelerator in the latex for several months in 1974 and 1975. This has been attributed to procurement problems associated with the oil embargo. They suggest that this could be the source of some of the reported discoloration. This may be indicative, however, of the vulnerability of condom colorants to the effects of improper ingredients in the powder or lubricant.

8. Conture/Conform shipped to Bangladesh and Thailand experienced discoloration. Akwell replaced heptene-based discolored condoms in Bangladesh in the fall of 1976. The Thai CBFPS program has 150 cases (80 gross) of Conture which they will not use. Akwell acknowledges that heptene-based accelerator (no longer in use) could contribute to brittleness as well.

9. Akwell has used starch as the finishing powder since early in mid 1975 ostensibly to reduce the possibility of brown spots which appeared in lycopodium powder. According to Akwell, Japanese condoms which are finished with lycopodium powder may have need for less powder during factory processing as they are more heavily cured than Akwell's. (The lighter cure permits a longer shelf life under normal storage as part of the curing process continues after manufacture). With time, however, the strength of the rubber deteriorates after 3 or 4 years).

F. COLOR

1. The value of colored condoms as a consumer attraction varies from country to country.

(a) Jamaica - Distributor salesmen and retailers were skeptical about consumer interest in various colored

condoms. Durex Shadow (black) were having difficulty in sales (perhaps because they are the most expensive condoms on the market.) Durex Gossamer are natural latex without color and were well received but they are no longer being imported. The CB program Panther is the predominant brand.

(b) Thailand - Colored condoms impart strong brand identification to Rainbow and provide good promotional impact for the CBFPS program.

(c) Bangladesh - Colored condoms attracted consumer interest initially in the CB program. As the government will be distributing free Tahiti in great quantities, the single color (red) in the Raja plastic package is very important for brand identity.

(d) Pakistan and others - Durex and Sultan (Akwel) sold in commercial channels, are natural color and have a reputation for quality. The Pakistan government has recently contemplated a CB program and asked for Durex as their choice for the program according to S. Sinding AID/Islamabad.

(e) Sri Lanka - The CB program which has been successful has distributed natural color Durex Gossamer in the Preethi pack.

(f) However several manufacturers such as London Rubber, Fuji, Sagami, Okamoto as well as Akwell now offer one or more brands with color in regular commercial sales.

They all apparently see a commercial value in doing so.

2. No clear independent tests have evaluated the long term affects of color in general or certain specific colors on product strength when stored under adverse conditions and with different kinds of packaging. However, color is now widely used and some of the manufacturers may have explored this. It is important to note that Akwell has acknowledged that the use of a heptene based powder resulted in discoloration. The question that needs answering is whether color as an additive weakens latex significantly under adverse conditions compared to natural latex.

3. There have been expressions by program administrators and Aid Population Officers that certain colors have been the source of breakage. No reasonable evidence exists, to support these concerns.

(a) Jamaica - CB program people thought the red color was the source of breakage. In the few condoms that had lower tensile strength at failure, red predominated but not significantly, particularly since the total sample lot tested acceptably.

(b) Thailand - It was thought the blues, greens and blacks broke more readily although this also is unsupported.

(c) New York City - An employee of the Human Resources Administration related to the investigator that 3 years ago red condoms had been identified with breakage among Federally supplied product to OEO family planning programs.

G. STORAGE AND DISTRIBUTION

1. Present warehousing in the programs visited, vary from excellent to seriously deficient for storage of condoms more than a year in humid, tropical countries.

(a) Thailand - The CBFPS program has over 60,000 gross of condoms (80 gross shipping cases) stored in a public warehouse which is a steel shed without adequate circulation for condoms. (Pills are also stored under the same conditions.) The cases are stocked 8 to 11 high, 10 deep and 8 wide. Temperatures midday when the warehouse was visited were listed in the newspaper at 91°F. Hot season temperatures often are well over 100 degrees F.

CBFPS packaged goods and a small amount of bulk Tahiti and Japanese condoms are stored at the CBFPS offices in buildings with space between ceiling and the roof and with circulation around the cases.

Government program condoms (Japanese) are stored on the ground floor of a five floor Ministry of Health Office building with air circulation around them.

The CBFPS Chiangrai (northern Thailand) store contraceptives in a brick shed but with a certain amount of air space but the temperature does not get as high as Bangkok or without relief.

(b) Bangladesh - The CB program bulk condoms and primary stocks of repackaged goods are stored on the

ground floor of a private residence with adequate circulation and 40 gross cases are stocked 6 to 8 high. The principal distributor for the CB program has good turnover in his stocks and has clean airy premises which are protected from direct heat. Other distributors have less desirable but adequate storage but most had a high turnover. A few were distributing older stocks.

The government free commodity program had previously used a private residence stuffed to the ceilings with pills and other supplies. Pills were noted stored on the porch in direct sunlight. No condoms were in the main warehouse as stocks had been depleted, but the Dacca District condom stocks were in an airy protected first floor of a house.

UNICEF is presently constructing a very spacious warehouse which may be ready for contraceptives in February or March (perhaps, later). AID/Dacca is planning on including dehumidifiers to protect contraceptives as this will be the primary supply for the country.

(c) Jamaica - The National Family Planning Board CB program and clinic program stores were in a large spacious warehouse but had 80 gross cases stocked 6 to 8 high, although steel shelves (immediately adjacent) were empty because the cases didn't fit into existing shelf spacing.

The CB program distributor stored repackaged condoms in a warehouse that was air conditioned most of midday.

2. Condoms may be warehoused 2 to 4 years from manufacture date before they are sent to distributors or get to retailers' shelves (Jamaica and Thailand). They may also remain 6 months or more on distributor and retailer shelves (Bangladesh and Thailand).

3. Programs may be overstocked based on usage levels and on an assumed 3 or 4 year expiry date which has yet to be determined.

(a) Jamaica - Total stocks as of September, 1977 may exceed 50,000 gross (natural and Tahiti) yet 58,000 gross of Tahiti were reported shipped to NFPB in late August, 1977. CB program usage will not exceed 5000 gross per year and clinic distribution appears to be dropping.

(b) Thailand - The CBFPS program presently has over 65,000 gross of Tahiti and about 150 (80 gross) cases of Conture (which they won't use). 50,000 gross of Tahiti are assigned to an FPIA program which has yet to begin for want of funding. Monthly CBFPS demand is 1500 gross retail sales and 500 to 1500 gross free promotional goods (per D. Gupta, IPPF CBD).

An expiry date of April/May 1978 has been written on the 80 gross cases in the public warehouse. Utilization by these dates is in doubt, particularly since IPPF is air freighting 6000 gross of Durex for an estimated 3 months use as a backup to the present stocks of Tahiti and Conture considered bad by the program.

(c) Bangladesh - CB program ordering and turnover appears to keep stocks fresh. The government program is receiving 400,000 gross in December 1977 and an additional 400,000 is expected in March. AID/Dacca expects use to be 30,000 gross per month and attributes the present 20,000 gross monthly use to condom shortages. If program condom uptake expectations are not realized, however, the quality of warehousing may become very significant.

4. There are no specific instructions establishing minimum criteria for warehousing in the tropics to provide guidance for program administrators.

5. The utilization of supply management systems to control against old stocks reaching the user and to provide for bad goods returns has not been sufficiently implemented.

(a) Bangladesh - Under AID/Dacca guidance, the government is utilizing an effective formal commodities control system down to the local level. Field stocks will not exceed 6 months while primary warehousing is to be handled centrally at the new UNICEF warehouse. The control system was designed by Jack Graves of the Center for Disease Control/Atlanta.

The PSI CB program holds primary stocks in their central warehouse as well as repackaged goods. Commodities are scheduled on a First in - First out (FIFO) basis. Turnover is good, but samples of old condoms were found on retailer shelves by the investigator. The checkup for old stocks is on an ad hoc basis.

(b) Jamaica - The CB program distributor uses FIFO in releasing repackaged stock to retailers. Since the NFPB warehouse stocks are piled together both in the CB area and for the clinic goods, it is doubtful that FIFO is used. No system for return of old stock was evident.

(c) Thailand - CBFPS repacked condoms are kept at the offices and minimal stocks are in the field. However, unpacked strips (May 75 manufacture) were observed in Chiangrai for the small village program and had been there for 1 year. It seems difficult to control CBFPS inventories with FIFO with the massive bulk of stock in the public warehouse, much of which is inaccessible.

(d) Mr. A. Griffiths of IPPF/London has designed a supplies control manual for the affiliates. Whether this is well utilized is not known, but IPPF has a staff member visiting affiliates on supply problems which provides followup on stocking controls..

H. SPECIFICATIONS

1. Neither the past nor recently instituted GSA specifications for condoms require any special packaging (or packing) for products to be shipped to and stored in tropical countries. ASTM and the International Standards Organizations (ISO) both simply require "suitable packaging" but set no conditions which are to be met.

(a) The effects of heat and humidity on individual package integrity have not been evaluated.

(b) The use of internal bagging in 100 or 144 piece paperboard container has not be considered.

(c) The rigidity of the cartons and shipping cases to withstand the rigors of overseas shipment and careless warehousing are not dealt with.

2. The new GSA specifications are oriented to standard commercial packaging which generally means temperate zone conditions.

3. Present GSA specifications set criteria for levels of lubricant but do not define the maximum amount of powder which may be applied to a condom. The proportion of powder to lubricant is also not defined.

4. The present and previous GSA specifications do not require any tests of packaged condoms in a wet box and vacuum chamber to monitor packaging material and seal integrity whether the packaging material is foil laminate, polyethylene or cellophane.

5. Present specifications do not require that condoms be free of unpleasant odors and that they be relatively easy to unroll immediately after packaging and after accelerated aging. U.S. government purchased Korean condoms observed in Thailand and Bangladesh had an unpleasant smell and were very difficult to unroll. These difficulties were not observed in Akwell, London Rubber or Japanese condoms.

6. Both GSA's new and old specifications differ with ASTM on the method for conducting water leakage tests. The ASTM specification is broader. After filling the condom with 300 ml. of water, ASTM permits drying and visual inspection. GSA expects the condom to be rolled on blotting paper. Akwell's water test does not conform to GSA, but falls within ASTM requirements. GSA Technical Operations Branch advise that they use the blotting paper in their own laboratory in Fort Worth and Akwell's results have been corroborated.

The Swedish and British specifications require the blotting paper test. Tahiti condoms are sold in these countries and have passed Customs testing which appears to be a further corroboration.

I. FIELD SAMPLING AND TESTING

1. There is no system for periodically checking, sampling and testing condoms after they have been in a country for one or two years or more. Program administrators need the reassurance of field quality control.

2. The sampling procedure in the GSA specifications for tensile strength and water test are related to immediate post-manufacture and post-packing identification of faulty batches.

There is no "rough and ready" sampling procedure applicable to large quantities that may be stored in a recipient country and upon which doubt of quality may arise. The stocks may consist of many different batches and lots.

(a) Thailand - Approximately 68,000 gross of Tahiti were under suspicion. 2,000 pieces were sampled for water test and 1700 pieces for tensile strength under randomized procedures (which were only approximated) to conform to the GSA specification.

The value of finding a number of failures beyond those allowed in the specification is somewhat doubtful as we are dealing with many batches buried in many lots which are almost impossible to segregate on the first sampling. (Testing by the investigator and MacMillan Research was conducted on a sub-sample only for tensile strength as the primary concern was whether the condoms had deteriorated from aging in tropical conditions.)

3. Initial field sampling and testing may have to be considered as a screening process to be followed with a more segregated sampling process if significant failures occur initially. This would avoid excessive scrapping of condoms if the initial testing does not demonstrate conclusively that the lot from which the sample has been taken is either acceptable or unacceptable.

VI. SAMPLING PROCEDURE AND TEST RESULTS

A. SAMPLING

Initially, without guidelines for sampling different lots and different batches (colors) in the field, the investigator elected to use the sampling set forth in the old GSA specification for water leakage and air burst tests for the product taken from the Jamaican CB program NFPB warehouse stocks. In addition samples were taken for tensile strength tests in accordance with the new GSA specification (per Section 6 of ASTM D-3492-76).

The quantities sampled were quite manageable for tests supervised by MacMillan Research Ltd. of Atlanta and performed at Akwell's laboratory in Dothan, Alabama. The tests were closely observed by Mr. S. Schmalhorst of MacMillan and for a short period by the investigator.

Subsequently the utility of the air burst test was deemed inappropriate since GSA had switched to ASTM tensile testing (as has ISO and the British Standards Institute) as a measure of aging and rubber strength. The water leak test, which was passed by Jamaican condoms (Sept/Oct 1975) seemed unnecessary for subsequent testing on Thai and Bangladesh condoms; again because we wish to explore the effects of time and environmental conditions on the rubber which is best measured by tensile testing.

Without the availability of the MIL-STD-105 the GSA sampling was used which produced 2000 pieces for tests (not conducted) and 1700 pieces for tensile from the Thai CBFPS warehouse Tahiti lot of 67,200 gross. The Bangladesh CB (PSI) program sample for tensile at 25 pieces per 1000 gross was over 500 pieces.

These sample sizes were unmanageable for testing from cost, time and manpower availability viewpoints. The MIL spec was consulted for a meaningful sample for large lots. At the S-3 level Table H, which approximates the ASTM 1½% Acceptable Quality Level, calls for 50 pieces as the sample. If two pieces pass the lot as acceptable, three pieces suggests reject.

The ASTM tensile strength and elongation at break for samples tested 12 months after manufacture in the as sampled condition are:

Tensile Strength		Elongation at Break	
min MPa		min %	
mean	Specimen	mean	Specimen
17	15	700	625

B. TEST RESULTS - FROM DATA BY MACMILLAN RESEARCH

1. Jamaica

a) Akwell Tahiti condoms sampled from the Jamaican CB program government warehouse and the CB distributor's warehouse readily passed the ASTM tensile strength and % elongation at break test both for the mean of the sample and for any individual specimen.

b) The appearance of the Tahiti condoms was good.

2. Thailand

a) Tahiti condoms sampled in the CBFPS Boonma public warehouse, the CBFPS office warehouse and in retail shops passed the ASTM requirements for tensile strength with a significant margin.

b) The appearance of the sampled Tahiti from Thailand generally not satisfactory. Occluded powder on the condoms in the public warehouse was noted as moderate spotting 50%, moderate, even

formation 20% and none 30%. Moderate occlusion may make the condoms appear "moldy" but not affect their strength.

Heavy spotting was noted on retail purchases.

(c) There was no evidence of offensive odors from condoms with occluded powder.

(d) Japanese condoms supplied by the U.S. and the Japanese government failed either the ASTM specification for tensile strength for the mean of the sample or an excessive number of failures below the ASTM individual specimen requirement. The Japanese condoms passed for % elongation at break, however, the Japanese condoms showed no evidence of occluded powder.

(e) Akwell Samoa purchased from retailers and an Akwell "me-to" for Tahiti at approximately the same time as Tahiti passed ASTM tests and showed no occlusion of powder.

3. Bangladesh

(a) Tahiti (Raja packaged) purchased from retailers and distributors passed the ASTM tensile strength requirements with considerable margin.

Tahiti sampled from the PSI warehouse readily passed the ASTM tensiles for the mean. One specimen (at 13.4 MPa) fell below the .15 MPa allowed for an individual specimen but according to MIL-STD-105 the lot is acceptable with two or less individual failures. The other pieces tested were generally well above the minimums.

(b) Strips of Tahiti from the PSI warehouse were observed as 70% light to no powder occlusion, 20% moderate and 10% heavy occluded powder.

c) There was no evidence of offensive odors from those Tahiti having heavy occluded powder.

4. General

a) One condom with heavy occluded powder was stained and examined under a microscope. No microorganisms were observed.

b) A Tahiti and a Japanese condom were examined for thickness at various locations, with a micrometer.

Location	<u>2</u>	<u>4</u>	<u>6</u>	<u>7</u>	<u>9</u>	
Tahiti	.065	.060	.070	.065	.050	mm.
Location	<u>2</u>	<u>3</u>	<u>5</u>	<u>7</u>	<u>9</u>	
Japanese	.070	.065	.060	.050	.050	mm.

(Location #1 is the closed end.)

VII. CONCLUSIONS

A. Akwell produced condoms appear to have met the various GSA specifications under the GSA Quality Assurance Program. The condoms supplied to AID through GSA were produced, tested and packaged on the same machinery used for their commercial production. Since GSA periodically checks Akwell's quality in its own laboratory, it is unlikely that Akwell will respond to being held accountable for the difficulties encountered in shipment or in countries with poor storage conditions.

B. An area of considerable doubt is whether Akwell's standard commercial packaging is suitable for long term storage in humid tropical environments. The GSA specifications do not make any special requirement for packaging which may be necessary for condoms going to AID recipient countries. Akwell might be held accountable for packaging and excess powder "which detract" from condom appearance, as required by the GSA specifications.

C. Tahiti condoms sampled in the Jamaica CB program passed tensile strength tests and are acceptable.

D. Between 20% and 50% of Tahiti condoms in the Thai program may not be acceptable to sell in competitive market from an appearance standpoint. Since the sample passed the ASTM tensile strength tests, the entire 67,000 gross in the Boonma warehouse are acceptable and should not be scrapped. All but the most unacceptable in appearance should be used in the CBFPS or government program.

E. Tahiti condoms in the Bangladesh CB program exhibited only moderate occluding of the powder in the lubricant and with

high turnover get used quickly. The condoms passed tensile strength tests and distribution should continue with existing stock.

F. Akwell condoms of about the same age + 9 months seem to be considerably stronger than sampled Japanese U.S. purchased and Japanese gifts to the Thai government. The Japanese condoms were not significantly thinner than Akwell Tahiti.

G. In-country storage under adverse conditions are less than appropriate but few guidelines have been distributed to describe what is appropriate.

H. Procedures for field sampling and testing of suspected condoms are not in existence.

I. No governmental or international standards have been established for packaging or control of packaging.

J. There has been no documented evaluation of the effect of color as additive to latex when subjected to adverse conditions and with different powder and lubricants. Apparently color has not affected Tahiti strength or durability.

K. CB programs may be particularly vulnerable to a significant number of consumer complaints of bad product. Poor condom publicity might jeopardize pill sales as well.

L. There are no guidelines circulated regarding expiring dates for condoms stored and distributed in specific local adverse conditions.

M. Akwell's manufacturing process may at times load condoms with too much powder (finishing dressing) or too much lubricant which results in clumping of the powder in contrast with condoms produced by other manufacturers which do not appear to have this difficulty.

VIII. RECOMMENDATIONS

The following recommendations have not been evaluated in terms of cost effectiveness but rather are being submitted to serve as the basis for further action to assure that sound products be received by the consumer. It is suggested that those recommendations that particularly require research and development be cost estimated to determine whether the research and the potential increase in commodity expenditures are worth proceeding with.

A. GENERAL RECOMMENDATIONS

1. It is desirable to specify minimum standards for the individual condom packaging (wrapper) in regard to vapor and gas transmission rates under aging in simulated tropical conditions of elevated temperature and humidity. It may be appropriate to contract with a university or independent engineering laboratory to screen packaging materials by composition, material thickness, and type of seal by testing packaged condoms in a wat box and a vacuum chamber.

2. It is desirable to develop standards for the maximum amount of powder or starch to be applied in finishing condoms after dipping and before testing and packaging. The GSA specification now includes minimum and maximum levels for the lubricant; this could be extended to powder as well.

3. AID should specify paperboard carton (for 100 or 144 pieces in strips of 3) with greater rigidity to protect condoms better than flat cartons now used by Akwell. This carton is the sole protection to bulk strips in the field in programs providing condoms free in clinics or from field workers or other paramedical personnel.

4. It is essential to specify a sealed internal plastic or foil laminate liner within the 100 piece paperboard carton to provide moisture protection until the condoms are distributed by field workers or clinics or until the CB programs repackage them. (This may be a useful expedient instead of the more elaborate Recommendation #1).

Another barrier against moisture would be a sealed internal plastic liner in the 40 gross or 40 one hundred piece shipping case to further protect against moisture.

5. It is essential that recommendations for minimum criteria for storage be developed. Recipients should be advised of the criteria but instructions should also be included on the outside of the 40 carton shipping case.

6. The shipping case now has the manufacturing date stamped on the outside but recipients and in-country advisers should have guidelines on how to determine expiry dates based on local conditions, relating to various storage conditions.

7. CB programs should stamp the manufacturing date and repacking date on the outside of display dispensers and arrange a system of collecting old goods that remain on wholesaler and retailer shelves too long. This should be implemented immediately.

8. (a) National programs should establish supply systems similar to that designed by J. Graves of CDC for Bangladesh to control against stocks remaining out too long in local warehouses and with field workers and in clinics.

(b) Smaller programs may use a system similar to that designed by A. Griffiths of IPPF and described in IPPF's supply manual modified to include return of old goods.

9. Both CB and government programs should provide training to warehouse personnel emphasizing the importance of first-in - first-out scheduling commodities and supplies.

10. When colored condoms are supplied, the clear window side should have an overprint which would reduce the amount of ultraviolet light (sunlight or fluorescent) reaching the condom but which would permit the consumer to identify the color. A side benefit would be that any minor occlusion of powder would not be as evident as with the clear window.

11. A procedure for sampling condoms of doubtful condition in program warehouses should be developed so that testing may be performed by region, bilateral or international agencies. Defective products should be removed. If they are not defective, strong reassurances should be provided to administrators of condom suitability.

12. The GSA spec, as a matter of course, should include statements that there be no unpleasant smell and that the condoms should be able to be unrolled readily, although Akwell or other U.S. condoms have not had such difficulties.

13. As condoms packaged in foil laminate may have greater shelf life and better appearance, an evaluation of the cost effectiveness of using foil either for both sides or one side of the package should be made.

14. AID/Washington should consider negotiating with Akwell regarding the sharing of costs for disposing of 150 cases (80 gross) of Conture still in the CBFPS public warehouse in Bangkok. Undoubtedly there are two factors to be considered; namely, Akwell's use of heptene based accelerator and poor storage conditions.

15. AID/Washington as the largest purchaser of condoms worldwide should have its own representative or observer at the meetings under the International Standards Organization sponsorship in which condom standards are discussed.

B. RECOMMENDATIONS BY COUNTRY

Jamaica

1. NFPB personnel should attempt to track down and record reports of breakage in both CB and clinic distribution. A certain number of complaints will occur. It is desirable to identify an accelerating complaint rate.

2. The NFPB should develop and implement supply controls in CB and clinic programs to avoid old stock being used.

3. NFPB and AID/Kingston should establish at what age stocks are to be called back or not distributed, in consultation with manufacturer or by periodic testing.

4. NFPB could improve storage conditions (stocking) in the NFPB warehouse by using the empty steel shelves. The 80 gross cases should not be stocked more than five high. Warehouse personnel should be trained in first-in - first-out scheduling.

5. Manufacturing and repackaging dates should be stamped on outside of dispensers so that old stock can be identified and removed.

6. Since Panther brand is well known, advertising for the CB program should now emphasize quality and the fact that the condoms are sold in Great Britain, the U.S. and around the world. Customer confidence needs to be reinforced.

7. A review of condom utilization by NFPB and AID should be undertaken to determine if condom stocks will be used in reasonable time to permit older condoms to be distributed so that forthcoming 1978 procurement will be realistic.

Thailand.

1. AID and CBFPS should evaluate the results of the tensile strength tests of Tahiti sampled at various points in the CBFPS supply system.

- If failures are excessive per the ASTM specification the condoms should be scrapped after retest so that the program will not be jeopardized. If failures are not excessive CBFPS should screen for more serious instances of occluded powder as condoms are repacked. Condoms that are sound mechanically and in good appearance should be used as \$150/200,000 is at risk if they must be scrapped.
- If moldy looking condoms are unacceptable to CBFPS, regardless of sound mechanical condition, then they could be used in the government programs for free distribution. (AID/Bangkok projects 58,000 gross requirement for next year).

2. AID and CBFPS should establish expiry dates for acceptability of condoms under local conditions.

3. It is essential that condoms be stored in a better warehouse as soon as possible but certainly before the next hot season and rainy spell.

4. The FPIS funded program for which 50,000 gross are in reserve and now in count-down to a "fictitious" product expiry date of April 1978 should commence soon. The condoms, if satisfactory, should be used no later than April 1979.

5. It would be desirable that annual needs, including pipeline filling for all programs should be filled on no more than a year or ½ year in country storage basis with followup of requirements from temperate zone warehouses -- at least until local warehousing improves significantly.

6. CBFPS display cartons should have the manufacturing date and repacking date stamped on the outside so that old stocks at the retail level can be recalled.

Bangladesh

1. CB (PSI) turnover is 10 to 12,000 gross per month. Stocks arrive with about 6 - 12 month supply and 2 to 3 months in the main warehouse. This supply mode should continue.

2. CB display cartons should have dates of manufacture and repackaging stamped on them so that slow moving old stocks may be removed from retailer or wholesaler shelves.

3. Assuming condoms sampled by the investigator (only 1 to 2 years old) are mechanically sound, visual inspection should continue for seriously occluded powder on condoms being repacked in Raja 3 piece cartons.

4. 400,000 gross of colored condoms for the government program will have arrived in December 1977. With projected maximum usage (by AID/Dacca) at 30,000 gross per month for some time, at least a year's supply will be available. AID/Washington should consider storing an additional 400,000 gross expected for March in a more temperate zone and then make shipment to arrive after the rainy season in Bangladesh next year. Utilization rates should be reviewed before the second shipment is authorized.

5. Every effort should be made to expedite the completion of the new UNICEF warehouse. The present warehouse in Dacca is not adequate for handling program supplies - condoms or pills. The Cittagong go-down that V. Peterson AID/Dacca has rented should be considered as only a temporary expedient.

6. V. Peterson's plan to hold supplies in a good central warehouse and less than 6 months in the district should, in the future, protect the commodities.

APPENDICIES

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MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

JAMAICAN RB

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

October 17, 1977
Analysis Number:
8-18-10 Y

LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Only a tensile test was performed on these samples. These are a composite of condoms taken from the NFPB warehouse. There were 25 pieces taken from each 1000 gross; there were 3000 gross in all. This resulted in 75 pieces for testing. The samples are also noted by color.

Sample Markings: Tahiti samples from NFPB warehouse for tensile test (25/1000 gross) RB 9/14/77

<u>Color</u>	<u>F(n)</u>	<u>W(mm)</u>	<u>t(mm)</u>	<u>D(e)</u>	<u>T(MPa)</u>	<u>E(%)</u>
Blue	70.4	20	.050	379	35.2	851
Pink	85.2	20	.060	458	35.5	1000
Green	77.6	20	.050	394	38.8	879
Black	74.5	20	.050	360	37.3	815
Yellow	92.2	20	.060	359	38.4	813
Blue	95.6	20	.050	411	47.8	911
Pink	32.7	20	.060	381	13.6	855
Green	73.6	20	.055	364	33.5	823
Black	80.0	20	.070	354	28.6	804
Yellow	85.1	20	.060	402	35.5	894
Blue	70.6	20	.050	384	35.3	860
Pink	52.3	20	.070	432	18.7	951
Green	79.4	20	.065	391	30.5	874
Blue	104.4	20	.060	402	43.5	894
Pink	75.4	20	.060	463	31.4	1009
Yellow	76.8	20	.060	357	32.0	809
Green	55.8	20	.070	358	19.9	811
Black	78.6	20	.060	387	32.8	866
Blue	99.9	20	.060	405	41.6	900
Pink	45.4	20	.050	439	22.7	964
Yellow	90.3	20	.070	392	32.3	875
Green	78.6	20	.060	410	32.8	909
Black	90.2	20	.060	384	37.6	860
Blue	74.6	20	.050	398	37.3	887
Pink	43.5	20	.070	426	15.5	940
Yellow	71.0	20	.050	373	35.5	840
Pink	58.0	20	.060	459	24.2	1002
Black	77.7	20	.075	365	25.9	825
Yellow	101.8	20	.065	381	39.2	855
Pink	51.8	20	.060	416	21.6	921
Yellow	79.0	20	.050	410	39.5	909

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P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Mr. Raymond Belsky

(2)

October 17, 1977

<u>Color</u>	<u>F(n)</u>	<u>W(mm)</u>	<u>t(mm)</u>	<u>D(e)</u>	<u>T(MPa)</u>	<u>E(%)</u>
Pink	62.8	20	.060	445	26.2	975
Yellow	80.2	20	.060	369	33.4	832
Pink	71.1	20	.065	457	27.3	998
Yellow	80.3	20	.060	387	33.5	866
Pink	44.5	20	.060	398	18.5	887
Green	66.3	20	.070	348	23.7	792
Blue	104.5	20	.060	405	43.5	900
Black	80.1	20	.065	359	30.8	813
Yellow	93.3	20	.060	376	38.9	845
Black	80.9	20	.060	366	33.7	826
Pink	69.4	20	.070	434	24.8	955
Green	95.4	20	.070	386	34.1	864
Blue	73.4	20	.060	383	30.6	858
Yellow	50.2	20	.050	375	25.1	843
Black	82.2	20	.070	357	29.4	809
Pink	42.0	20	.060	415	17.5	919
Green	82.4	20	.070	398	29.4	887
Blue	64.7	20	.060	362	27.0	819
Yellow	55.9	20	.050	382	28.0	857
Black	63.0	20	.060	365	26.3	825
Pink	89.3	20	.060	459	37.2	1002
Green	109.1	20	.070	394	39.0	879
Blue	57.3	20	.050	364	28.8	823
Pink	52.5	20	.060	437	21.9	960
Yellow	71.4	20	.060	388	29.8	868
Black	69.2	20	.060	354	28.8	804
Green	81.8	20	.060	387	34.1	866
Blue	55.1	20	.070	358	19.7	811
Pink	56.3	20	.070	407	20.1	892
Yellow	74.9	20	.050	347	37.5	791
Black	67.1	20	.070	339	24.0	775
Green	79.3	20	.070	352	28.3	800
Blue	101.2	20	.060	400	42.2	891
Pink	61.2	20	.050	439	30.6	964
Yellow	82.5	20	.065	356	31.7	808
Pink	52.0	20	.060	454	21.7	992
Green	68.9	20	.070	368	24.6	830
Blue	62.8	20	.070	366	22.4	826
Yellow	67.7	20	.070	341	24.2	779
Black	53.6	20	.060	351	22.3	798
Pink	47.3	20	.060	444	19.7	974
Green	52.9	20	.060	369	22.0	832
Green	31.3	20	.070	315	11.2	730



- 2 -
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Mr. Raymond Belsky

(3)

October 17, 1977

<u>Color</u>	<u>F(n)</u>	<u>W(mm)</u>	<u>t(mm)</u>	<u>D(e)</u>	<u>T(MPa)</u>	<u>E(%)</u>
Green	64.3	20	.060	361	26.8	817

* * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.


Steve Schmalhorst
Chemistry

SS:dh



MACMILLAN RESEARCH, LTD.

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New York, New York 10023

Jamaica RB
October 17, 1977
Analysis Number:
6-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. A series of three tests were performed including tensile strength, air volume, and water test. The samples are also noted by color.

Sample Markings: DeCordova whse pop up Feb. 75 goods per BA mfg date RB 9/14/77

Tensile Strength: Twelve condoms were tested for tensile and elongation

<u>Color</u>	<u>F(n)</u>	<u>W(mm)</u>	<u>t(mm)</u>	<u>D(e)</u>	<u>T(MPa)</u>	<u>E(%)</u>
Blue	59.7	20	0.050	393	29.9	877
Yellow	61.6	20	0.060	375	25.7	843
Blue	41.0	20	0.060	368	17.1	830
Blue	56.2	20	0.055	389	25.5	870
Green	53.3	20	0.050	336	26.7	770
Blue	57.8	20	0.060	383	24.1	858
Yellow	59.2	20	0.070	343	21.1	783
Green	59.7	20	0.055	345	27.1	787
Blue	43.8	20	0.060	380	18.3	853
Green	63.0	20	0.040	339	39.4	775
Black	58.5	20	0.060	363	24.4	821
Green	52.2	20	0.050	341	26.1	779

Air Volume: Eight condoms were tested for air volume capacity. Each were filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Black	1.26
Green	0.98
Yellow	1.05
Blue	1.69
Green	1.11
Yellow	1.38
Blue	1.43
Yellow	1.28

Water test: 125 condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,
MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Steve Schmalhorst
Chemistry

MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061
Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

JANAIKA Lab
October 17, 1977
Analysis Number:
7-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. A series of three tests were performed including tensile strength, air volume, and water test. The samples are also noted by color.

Sample Markings: DeCordova whse from wall dispenser Oct. 74 mfg date IZ RB 9/14/77

Tensile Strength: Twelve condoms were tested for tensile and elongation

<u>Color</u>	<u>F(n)</u>	<u>W(mm)</u>	<u>t(mm)</u>	<u>D(e)</u>	<u>T(MPa)</u>	<u>E(%)</u>
Red	100.4	20	0.060	417	41.8	923
Blue	27.3	20	0.055	383	12.4	858
Pink	84.6	20	0.060	444	35.3	974
Blue	70.4	20	0.070	391	25.1	874
Red	45.8	20	0.055	333	20.8	764
Pink	65.7	20	0.055	404	29.9	898
Green	80.8	20	0.055	434	36.7	955
Pink	50.8	20	0.060	383	21.2	858
Red	69.7	20	0.060	373	29.0	840
Green	52.4	20	0.060	352	21.8	800
Blue	63.7	20	0.050	400	31.9	891
Blue	37.8	20	0.055	338	17.2	774

Air Volume: Eight condoms were tested for air volume capacity. Each were filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Green	1.15
Red	1.27
Blue	1.26
Green	1.32
Blue	1.50
Red	1.42
Blue	1.27
Green	0.98

Water test: 190 condoms were each filled with 300 ml. of water and were found to have 1 pin hole in one condom.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
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MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Janica EB

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

October 17, 1977
Analysis Number:
9-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case A1, Lot # 2549M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Green	1.16
Blue	1.40
Green	0.87
Pink	1.17
Green	1.04
Green	1.30
Black	1.02
Green	1.23

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Chemistry

SS:dh

MACMILLAN RESEARCH, LTD.

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Jamaica LLB

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

October 17, 1977
Analysis Number:
10-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case A2, Lot # 2642M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Yellow	1.28
Black	1.31
Black	1.28
Green	1.25
Pink	1.17
Green	1.26
Blue	1.10
Black	1.16

Water test: Ten condoms were each filled with 300 ml. of water and were found to have 1 pin hole in one condom.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Chemistry

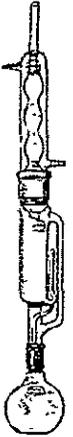
SS:dh

- 7 -
MACMILLAN RESEARCH, LTD.

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Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

Jamaica Lab
October 17, 1977
Analysis Number:
11-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case A3, Lot # 2643M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Pink	1.00
Black	1.08
Pink	1.79
Green	1.06
Pink	1.21
Green	1.67
Blue	1.50
Yellow	1.28

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
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Chemistry

SS:dh

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Jamieca RB

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

October 17, 1977
Analysis Number:
12-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case A4, Lot # 2639M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Green	1.20
Black	1.14
Yellow	1.22
Blue	1.62
Black	0.89
Green	1.17
Pink	1.32
Pink	1.23

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

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Steve Schmalhorst
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JAMAICA

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

October 17, 1977
Analysis Number:
13-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case A5, Lot # 2618M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Blue	1.27
Black	1.18
Yellow	1.36
Green	1.19
Blue	1.25
Yellow	1.11
Blue	0.87
Green	1.04

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

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Mr. Raymond Belsky
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New York, New York 10023

October 17, 1977
Analysis Number:
14-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case A6, Lot # 2638M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air:

<u>Color</u>	<u>Cubic Feet of Air</u>
Yellow	1.06
Pink	1.04
Green	0.96
Blue	0.75
Green	1.21
Blue	1.43
Blue	0.74
Black	1.38

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

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Jamaica

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

October 17, 1977
Analysis Number:
15-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case A7, Lot # 2613M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Black	1.13
Yellow	1.29
Pink	1.21
Blue	1.03
Blue	1.46
Green	1.31
Black	1.08
Black	1.17

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

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SS:dh

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Jamaica

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

October 17, 1977
Analysis Number:
16-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case A8, Lot # 2625M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Pink	1.41
Pink	1.25
Pink	1.30
Yellow	1.04
Blue	1.33
Pink	1.48
Green	0.63
Green	1.17

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
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SS:dh

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290 West End Avenue
New York, New York 10023

Jamaica
October 17, 1977
Analysis Number:
17-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case A9, Lot # 2682M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Pink	1.46
Green	1.15
Pink	1.51
Blue	1.19
Pink	1.40
Yellow	1.13
Pink	1.11
Blue	1.38

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Steve Schmalhorst
Chemistry

SS:dh

- 15 -
MACMILLAN RESEARCH, LTD.

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Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

JAMAICA
October 17, 1977
Analysis Number:
18-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case A10, Lot # M2665, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Pink	1.01
Black	1.18
Pink	1.24
Black	1.16
Blue	1.33
Blue	1.07
Pink	1.13
Green	1.22

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst

Steve Schmalhorst
Chemistry

SS:dh

- 16 -
MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

JAMAICA
October 17, 1977
Analysis Number:
19-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case All, Lot # M2559, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Blue	1.33
Black	0.89
Blue	1.40
Yellow	0.94
Blue	1.43
Blue	1.38
Yellow	1.24
Blue	1.59

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst

Steve Schmalhorst
Chemistry

SS:dh

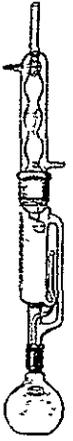
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P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Jamaica

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

October 17, 1977
Analysis Number:
20-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case A12, Lot # 2685M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Pink	1.47
Blue	0.78
Yellow	1.40
Pink	0.17
Green	1.05
Yellow	0.90
Blue	1.74
Green	1.16

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
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Chemistry

SS:dh

MACMILLAN RESEARCH, LTD.

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Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

Jamaica
October 17, 1977
Analysis Number:
21-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case A-13, Lot # M2606, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Black	1.20
Blue	1.61
Green	1.78
Green	1.26
Green	0.88
Blue	1.47
Yellow	1.09
Yellow	1.46

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
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Chemistry

SS:dh

MACMILLAN RESEARCH, LTD.

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Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

Jamaica
October 17, 1977
Analysis Number:
22-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case A-14, Lot # 2623M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Blue	1.21
Pink	1.28
Yellow	1.10
Yellow	1.42
Pink	0.83
Black	1.18
Yellow	1.46
Black	0.78

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Chemistry

SS:dh

MACMILLAN RESEARCH, LTD.

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JAMAICA

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

October 17, 1977
Analysis Number:
23-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case A-15; Lot # M2689, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Green	1.46
Pink	1.15
Blue	1.45
Black	0.86
Pink	1.07
Yellow	1.19
Blue	1.39
Black	0.84

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Chemistry

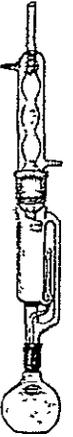
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Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

Jamaica
October 17, 1977
Analysis Number:
24-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case A-16, Lot # 2652M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Green	1.11
Black	1.25
Black	1.26
Green	1.39
Black	1.10
Pink	1.18
Black	0.81
Pink	1.19

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pinholes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Chemistry

SS:dh

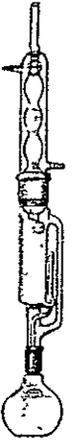
MACMILLAN RESEARCH, LTD.

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Jamaica

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

October 17, 1977
Analysis Number:
25-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case A-17, Lot # 2660M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Blue	1.36
Yellow	1.17
Blue	1.15
Yellow	1.04
Black	1.27
Yellow	1.18
Black	0.86
Blue	1.48

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Chemistry

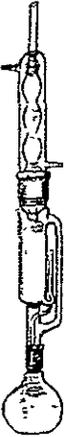
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Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

JAMAICA
October 17, 1977
Analysis Number:
26-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case A-18, Lot # 2663M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Black	1.30
Blue	1.14
Pink	1.09
Yellow	1.05
Green	1.30
Green	1.57
Pink	1.01
Black	1.26

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Chemistry

SS:dh

- 24 -
MACMILLAN RESEARCH, LTD.

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Mr. Raymond Belsky
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Jennica
October 17, 1977
Analysis Number:
27-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case A-19, Lot # 2684M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Blue	0.55
Blue	1.22
Pink	0.76
Black	1.30
Black	1.17
Blue	1.26
Black	1.28
Pink	1.31

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Steve Schmalhorst
Chemistry

SS:dh

MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

JAMAICA
October 17, 1977
Analysis Number:
28-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case A-20, LOT # 2644M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Pink	0.64
Green	1.45
Black	1.26
Blue	1.37
Yellow	1.22
Pink	1.28
Black	0.98
Blue	1.63

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Chemistry

SS:dh

MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

Jamaica
October 17, 1977
Analysis Number:
29-18-10-Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case A-21, Lot # 2594M, 40 Gross September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Green	1.01
Black	1.55
Pink	1.16
Blue	1.83
Black	1.36
Green	1.13
Yellow	1.42
Black	1.23

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,
MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Steve Schmalhorst
Chemistry

SS:dh

MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

JAMAICA
October 17, 1977
Analysis Number:
30-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case B-1, Lot # 2502M, October 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Blue	1.26
Pink	0.82
Yellow	1.40
Green	1.10
Blue	1.56
Black	1.32
Green	1.34
Yellow	1.49

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,
MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Steve Schmalhorst
Chemistry

SS:dh

MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

Jamaica
October 17, 1977
Analysis Number:
31-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NEPB warehouse. The samples are noted by color.

Sample Description: Case B-2, Lot # 2702M, October 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Black	1.27
Yellow	1.05
Black	0.62
Yellow	0.83
Pink	1.24
Yellow	1.32
Pink	1.23
Yellow	1.60

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,
MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Steve Schmalhorst
Chemistry

SS:dh

MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

JAMAICA
October 17, 1977
Analysis Number:
32-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case B-3, Lot # 2676M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Blue	1.48
Yellow	1.22
Pink	1.65
Blue	1.61
Green	0.85
Blue	1.40
Pink	1.56
Black	0.98

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Chemistry

SS:dh

- 30 -
MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

Janaka
October 17, 1977
Analysis Number:
33-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case B-4, Lot # 2691M, October 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Pink	0.99
Green	1.08
Green	0.95
Yellow	1.11
Black	1.25
Green	1.06
Pink	1.19
Yellow	1.24

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst

Steve Schmalhorst
Chemistry

SS:dh.

- 31 -
MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

JAMAICA
October 17, 1977
Analysis Number:
34-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NEFB warehouse. The samples are noted by color.

Sample Description: Case B-5, Lot # 2616M, October 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Pink	1.06
Black	1.13
Green	1.40
Black	0.68
Pink	1.10
Blue	1.47
Yellow	1.15
Pink	1.11

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,
MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst

Steve Schmalhorst
Chemistry

SS:dh

- 32 -
MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

Jamaica
October 17, 1977
Analysis Number:
35-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case B-6, Lot # 2646M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Green	0.96
Black	1.16
Blue	1.67
Yellow	1.19
Blue	1.46
Yellow	1.23
Pink	1.18
Green	1.05

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Steve Schmalhorst
Chemistry

SS:dh

- 33 -
MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

JAMAICA
October 17, 1977
Analysis Number:
36-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case B-7, Lot # 2690M, October 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Pink	1.33
Yellow	1.03
Blue	1.56
Blue	1.35
Pink	0.17
Blue	1.35
Black	1.18
Pink	1.61

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,
MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Steve Schmalhorst
Chemistry

SS:dh

- 34 -
MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

JAMAICA
October 17, 1977
Analysis Number:
37-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case B-8, Lot # 2699M, October 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Pink	1.17
Blue	1.46
Pink	1.28
Black	1.21
Pink	1.21
Yellow	1.30
Pink	1.43
Black	1.14

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Steve Schmalhorst
Chemistry

SS:dh

- 35 -
MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

Jamaica
October 17, 1977
Analysis Number:
38-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case B-9, Lot # 2671M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Yellow	1.40
Pink	1.37
Pink	1.34
Blue	1.31
Green	1.25
Blue	1.46
Yellow	1.55
Pink	1.42

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst

Steve Schmalhorst
Chemistry

SS:dh

MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

JAMAICA
October 17, 1977
Analysis Number:
39-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case B-10, Lot # 2657M, October 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Green	1.11
Pink	1.46
Green	0.89
Black	0.84
Blue	1.26
Black	1.20
Blue	1.76
Blue	1.47

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pinholes.

* * * *

Respectfully Submitted,
MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Steve Schmalhorst
Chemistry

SS:dh

MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

JAMAICA
October 17, 1977
Analysis Number:
40-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case B-11, Lot # 2629M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Blue	1.57
Pink	1.16
Yellow	1.04
Blue	1.58
Blue	1.51
Pink	1.25
Black	1.22
Green	1.24

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,
MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Steve Schmalhorst
Chemistry

SS:dh

MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

JAMAICA

October 17, 1977

Analysis Number:

41-18-10 Y

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case B-12, Lot # 2573M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Blue	1.49
Yellow	1.25
Green	1.02
Blue	1.35
Black	1.46
Pink	1.10
Pink	1.32
Yellow	1.75

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Chemistry

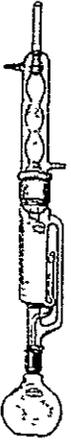
SS:dh

- 39 -
MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

JAMAICA
October 17, 1977
Analysis Number:
42-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case B-13, Lot # 2600M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Pink	0.88
Yellow	1.21
Blue	1.05
Black	1.18
Yellow	1.20
Green	1.21
Black	0.89
Pink	1.06

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Steve Schmalhorst
Chemistry

SS:dh

- 40 -
MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

Jannica
October 17, 1977
Analysis Number:
43-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case B-14, Lot # 2651M, October 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Green	1.01
Pink	0.98
Black	1.11
Yellow	1.35
Pink	1.80
Black	0.87
Pink	1.16
Green	1.19

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,
MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Steve Schmalhorst
Chemistry

SS:dh

MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

JRANICA
October 17, 1977
Analysis Number:
44-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case B-15, Lot # 2654M, October 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Pink	1.54
Black	1.22
Pink	0.83
Blue	1.24
Pink	1.41
Black	1.26
Blue	1.67
Black	0.91

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Chemistry

SS:dh

MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

JAMAICA
October 17, 1977
Analysis Number:
45-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case B-16, Lot # 2678M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Yellow	1.54
Pink	1.09
Yellow	1.66
Green	1.24
Blue	1.34
Yellow	1.46
Pink	1.11
Blue	1.36

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Steve Schmalhorst
Chemistry

SS:dh

MACMILLAN RESEARCH, LTD.

P. O. BOX 1305 • MARIETTA, GEORGIA 30061

Mr. Raymond Belsky
290 West End Avenue
New York, New York 10023

Jamaica
October 17, 1977
Analysis Number:
46-18-10 Y



LABORATORY STUDY ON CONDOM SAMPLES:

The following condoms were tested at the Akwell Industries plant in Dothan, Alabama on October 13, 1977. Air volume and water tests were performed. These samples came from the NFPB warehouse. The samples are noted by color.

Sample Description: Case B-17, Lot # 2693M, September 1975

Air volume: Eight condoms were tested for air volume capacity. Each was filled with air until bursting. The results recorded below are in cubic feet of air.

<u>Color</u>	<u>Cubic Feet of Air</u>
Blue	1.42
Pink	1.04
Yellow	1.25
Blue	1.27
Green	1.21
Blue	1.29
Pink	1.30
Blue	1.31

Water test: Ten condoms were each filled with 300 ml. of water and were found to have no pin holes.

* * * *

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.

Steve Schmalhorst
Chemistry

SS:dh



December 29, 1977

Mr. Raymond Belsky
210 West 70th Street
New York, New York 10023

Dear Mr. Belsky:

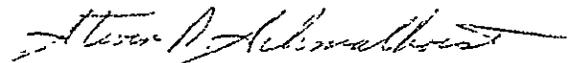
On December 27, 1977 testing was begun on condom samples at Akwell Industries in Dothan, Alabama. The condom samples were procured by Mr. Raymond Belsky from various places in Thailand and Bangladesh. Included were two samples of Japanese condoms. The objective of the testing was to determine the tensile strength and percent elongation of these condoms. The testing was completed on December 28, 1977 and the test results data was recorded.

The photocopies of the test results were forwarded to Mr. Raymond Belsky at 210 West 70th Street, New York, New York 10023. The original test results are maintained at Mac Millan Research, Ltd., P. O. Box 1305, 1221 Barclay Circle, Marietta, Georgia 30061.

Each copy of the test results are stamped with the name and mailing address of Mac Millan Research, Ltd. and initialed by Steven R. Schmalhorst, who was representing Mac Millan Research, Ltd. in Dothan, Alabama.

Respectfully Submitted,

MAC MILLAN RESEARCH, LTD.


Steven R. Schmalhorst
Microbiologist

SRS:dh

MACMILLAN RESEARCH, LTD.

Analytical & Consulting Chemists



P. O. BOX 1305
MARIETTA, GA. 30061
PHONE 427-3101

December 29, 1977

Mr. Raymond Belsky
210 West 70th Street
New York, New York 10023

Dear Mr. Belsky:

Various condoms were subjected to visual observation to note the presence of any excess powder forming on the condom. The condoms were in their packages and the observations were taken by looking through the clear side of the package. In addition, these observations are purely subjective and dependant upon the person or persons performing the observation.

These condom samples are related to the samples used for testing tesile strength and percent elongation at Dothan, Alabama on December 27, 1977.

CONDOM MARKINGS

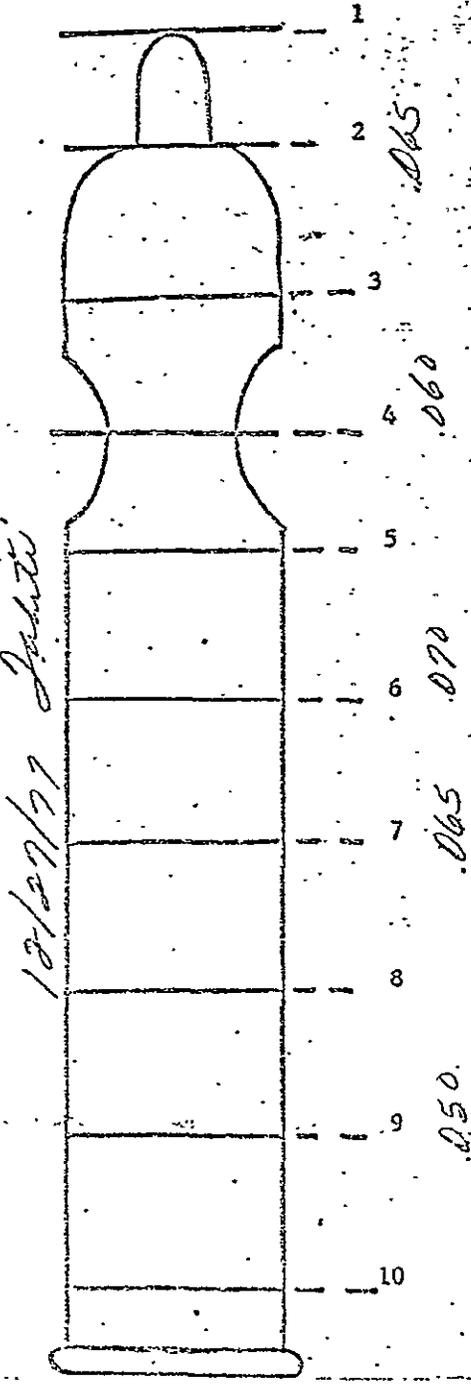
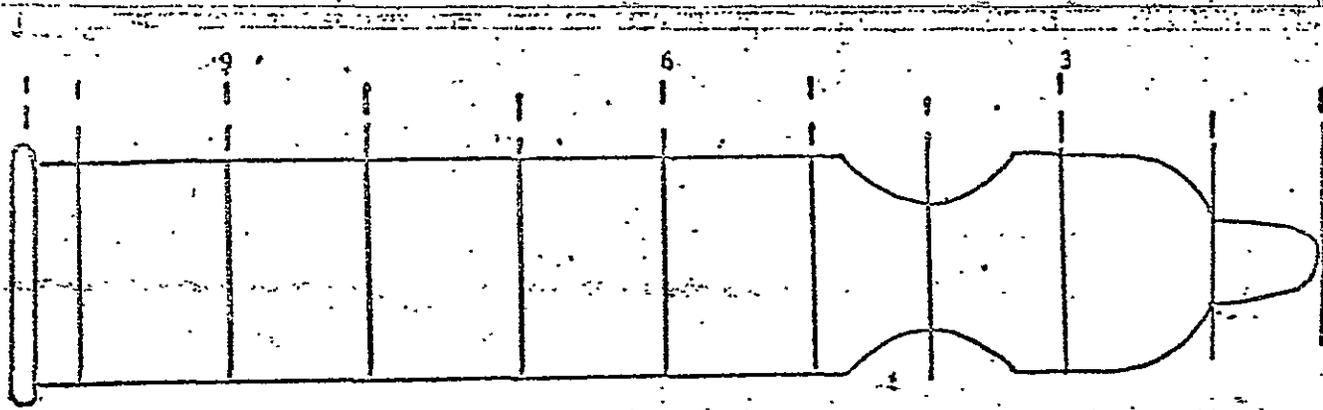
POWDER FORMATION

Somoa	None
Tahiti	Slight to Moderate Spotting
Japanese CPFBS Warehouse	None
U. S. Purchased Japanese Goods	None
Tahiti - Rainbow - Thai	Slight to Moderate Spotting
Tahiti - RAJA - Bangladesh	Moderate to Heavy, Even Formation
Tahiti, From Government Warehouse in Thailand	{ 50 % Moderate Spotting 20 % Moderate, Even Formation 30 % None
Tahiti - Rainbow From Chiang-Rai Rural Program	
Tahiti Strips From Bangladesh	
	Heavy Spotting
	70 % Light to None
	20 % Moderate
	10 % Heavy

Several condoms were inspected for any extraordinary odor. The condoms selected were in their packages and appeared to have been handled poorly. However, there was no indication of any unusual odor from either the outside or the inside of the packages. In addition, the inside of one of the packages was aseptically swabbed in an attempt to determine the presence of any microorganisms. The swabbing was applied to a slide and stained. The result of this test discovered no microorganisms however the presence of a crystalline matter presumed to be powder.

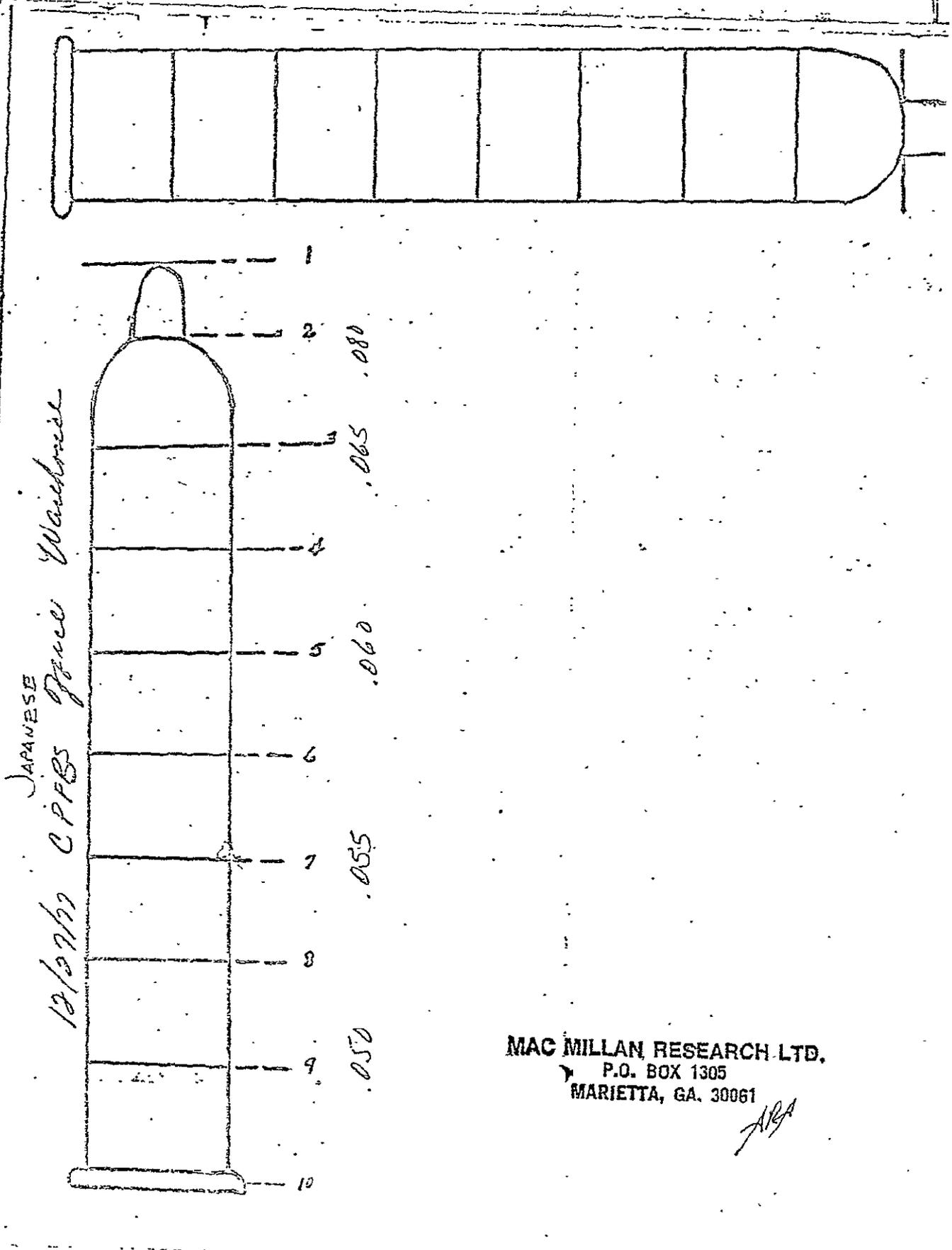
Respectfully Submitted,
MAC MILLAN RESEARCH, LTD.

Steven R. Schmalhorst
Steven R. Schmalhorst
Microbiologist



MAC MILLAN RESEARCH LTD,
 P.O. BOX 1305
 MARIETTA, GA. 30061

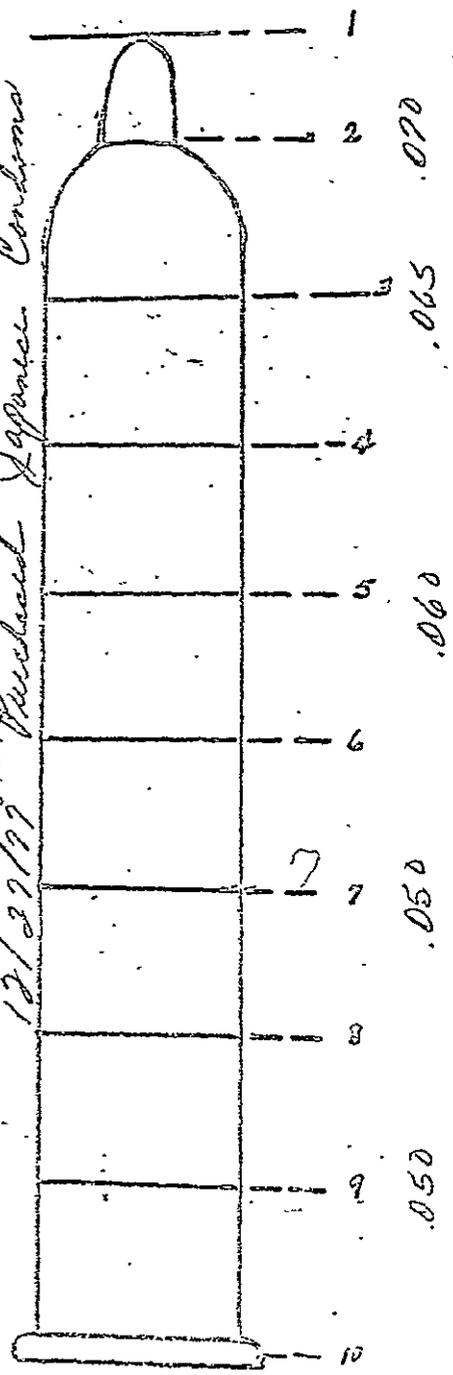
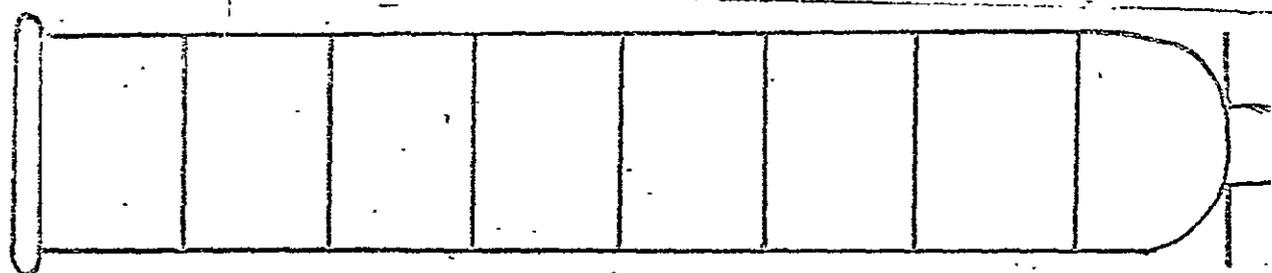
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MAC MILLAN RESEARCH LTD.
P.O. BOX 1305
MARIETTA, GA. 30061

ARA

12/22/57 U.S. Purchase Japanese Condens



MAC MILLAN RESEARCH LTD.
P.O. BOX 1305
MARIETTA, GA. 30061

Analysis No. 5-27-121

DATE MFG _____

TYPE GOODS Canture
52

DATE TESTED 12-28-77

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
1	94.0	20	.065	360	36.2	815
2	82.3	20	.070	352	29.4	810
3	80.0	20	.075	333	26.7	764
4	70.8	20	.060	354	30.0	804
5	70.4	20	.070	344	25.1	785
6	78.5	20	.065	373	30.2	840
7	64.7	20	.070	331	23.1	760
8	104.9	20	.060	394	43.7	879
9	101.6	20	.060	374	42.3	842
10	75.2	20	.065	388	28.9	868
11	72.4	20	.060	388	30.0	868
12	88.8	20	.070	377	31.7	847
13	75.5	20	.065	350	29.0	796

$T = \frac{F}{2 \text{ Wt.}}$

$E = 144 + 2D(e)$

X 100

106

Raja - Bangladesh Tobacco AB
9/76
11/76

Average Tensile ~~31.269~~ 32.752 (ARA)
Average Elongation ~~820.615%~~ 830.32 (ARA)

MAC MILLAN RESEARCH LTD.
P.O. BOX 1305
MARIETTA, GA. 30061
JRA

DATE MFG _____

TYPE GOODS Couture
52

DATE TESTED 12-28-77

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
14	86.6	20	.060	383	36.1	858
15	71.5	20	.065	381	27.5	855
16	114.1	20	.065	394	43.9	879
17	89.1	20	.060	379	32.1	857
18	94.4	20	.070	384	33.2	860
19	79.2	20	.065	361	30.5*	817
20	90.0	20	.060	377	37.5	847
21	77.4	20	.065	361	29.8	817
22	89.5	20	.065	374	34.4	842
23	69.6	20	.060	354	29.0	804
24	59.0	20	.060	332	24.6	762
25	115.6	20	.060	404	48.2	898

$$T = \frac{F}{2 \text{ Wt.}}$$

$$E = \frac{144 + 2D(e)}{100}$$

X 100

106

Raja
9/76
9/76

MAC MILLAN RESEARCH LTD.
P.O. BOX 1305
MARIETTA, GA. 30061
ARA

Analysis 15. 5-27-77

DATE MFG _____

TYPE GOODS NE

DATE TESTED 12-27-77

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
1	61.6	20	.060	350	25.7	796
2	38.4	20	.060	322	16.0	743
3	46.9	20	.060	327	19.5	753
4	48.1	20	.060	334	20.0	766
5	28.8	20	.060	301	12.0	704
6	48.0	20	.060	330	20.0	758
7	28.7	20	.060	290	12.0	683
8	28.3	20	.055	294	12.9	691
9	45.3	20	.065	329	17.4	757
10	47.7	20	.055	331	21.7	760
11	60.2	20	.060	352	25.1	800
12	34.8	20	.060	307	14.5	715
13	49.3	20	.060	342	20.5	781

$T = \frac{F}{2 \text{ Wt.}}$

$E = 144 + 2D(e)$

X 100

106

From CBFBS Office warehouse
Condom (Bi-Lateral) Japanese gift to Thai Ministry of Health
4 Cases 5 strips of 3 = 60 pcs

From 2, 100 gross

Nov. 8, 1977 sampling
Fuji Latex Co. LTD

MAC MILLAN RESEARCH LTD.
P.O. BOX 1305
MARIETTA, GA. 30061

Average Tensile 17.244
Average Elongation 733.8%

DATE MFG _____

TYPE GOODS NE

DATE TESTED 12-27-77

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
14	44.7	20	.060	327	18.6	753
15	37.9	20	.060	311	15.8	723
16	45.2	20	.060	321	18.8	742
17	29.8	20	.060	294	12.4	691
18	45.1	20	.060	323	18.8	745
19	43.2	20	.060	330	18.0	758
20	30.4	20	.055	304	13.8	709
21	48.3	20	.065	337	18.6	772
22	28.1	20	.060	287	11.7	677
23	44.2	20	.060	321	18.4	742
24	66.0	20	.060	344	25.4	785
25	38.1	20	.060	314	15.9	728
26	34.2	20	.060	319	14.3	738

$T = \frac{F}{2 \text{ Wt.}}$

$E = 144 + 2D(e)$

X 100

BEAC HILLAN RESEARCH LTD.

P.O. BOX 1365

MARIETTA, GA. 30061

Handwritten initials/signatures

DATE MFG _____

- 54 -

TYPE GOODS NEDATE TESTED 12-27-77DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t'(mm)	D(e)	T(MPa)	E(%)
27	36.8	20	.060	318	15.3	736
28	52.2	20	.055	338	23.7	774
29	52.0	20	.055	340	23.6	777
30	31.4	20	.055	302	14.3	706
31	35.2	20	.055	305	16.0	711
32	39.4	20	.060	318	16.4	736
33	35.7	20	.065	304	13.7	709
34	46.0	20	.060	326	19.2	751
35	41.2	20	.060	326	17.2	751
36	33.6	20	.060	295	14.0	692
37	34.5	20	.060	305	14.4	711
38	55.7	20	.060	344	23.2	785
39	63.1	20	.050	347	31.6	791

$$T = \frac{F}{2 \text{ Wt.}}$$

$$E = \frac{144 + 2D(e)}{106}$$

$$X = 100$$

106

MAC MILLAN RESEARCH LTD.

P.O. BOX 1305

MARIETTA, GA. 30061

Al. ... *JA*

DATE MFG _____

TYPE GOODS NE

DATE TESTED 12-27-77

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
40	39.3	20	.050	327	19.7	753
41	48.9	20	.060	322	20.4	743
42	51.9	20	.060	326	21.6	751
43	26.6	20	.060	284	11.1	670
44	31.9	20	.060	299	13.3	700
45	29.8	20	.060	289	12.4	681
46	38.7	20	.060	312	16.1	725
47	33.5	20	.060	309	14.0	719
48	29.4	20	.060	292	12.3	687
49	23.0	20	.060	285	9.6	674
50	24.8	20	.055	291	11.3	685

$$T = \frac{F}{2 \text{ Wt.}}$$

$$E = 144 + 2D(e)$$

X 100

106

MAC MILLAN RESEARCH LTD.
P.O. BOX 1305
MARIETTA, GA. 30067
ARA

DATE MFG _____

TYPE GOODS NE

DATE TESTED 12-27-77

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
1	28.6	20	.060	321	11.9	742
2	31.6	20	.050	317	15.8 ⁴⁵ 13.8	734
3	28.1	20	.055	317	12.8	734
4	29.5	20	.060	312	12.3	725
5	31.1	20	.050	314	15.6	728
6	20.4	20	.055	289	9.3	681
7	29.4	20	.060	311	12.3	723
8	32.5	20	.050	332	16.3	762
9	30.9	20	.060	323	12.9	745
10	35.6	20	.050	319	17.8	738
11	30.4	20	.050	321	15.2	742
12	34.3	20	.060	325	14.3	749
13	31.6	20	.055	320	14.4	740

$T = \frac{F}{2 \text{ Wt.}}$

$E = 144 + 2D(e)$

X 100

106

U.S. Purchased
Japanese Condoms mfg wR

6 strips of 3 F 002 PB Feb. 1975
6 strips of 3 F 002 PE Feb. 1975

Sampled 8/Nov/77

From 1,300 gross

MAC MILLAN RESEARCH LTD.
P.O. BOX 1305

MARIETTA, GA. 30061

Average Tensile 14.308
Average Elongation 736.6%
JLJ AKA

TESTED 12-27-77

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
14	34.3	20	.055	328	15.6	755
15	29.3	20	.050	305	14.7	711
16	30.3	20	.055	331	13.8	760
17	39.8	20	.055	335	18.1	768
18	30.0	20	.050	309	15.0	719
19	32.7	20	.060	313	13.6	726
20	18.4	20	.050	293	9.2	689
21	40.9	20	.055	328	18.6	755
22	31.3	20	.050	318	15.7	736
23	34.9	20	.060	334	14.5	766
24	21.8	20	.050	308	10.9	717
25	34.1	20	.050	336	12.1	770

$$T = \frac{F}{2 \text{ Wt.}}$$

$$E = 144 + 2D(e)$$

$$\times 100$$

106

U.S. Purchased

Japanese Condoms 4mg wk

6 strips of 3 F012 Pb Feb 1975

6 strips of 3 F012 PE Feb 1975

Sampled 8/Nov/77

from 1,300 gross

MAC MILLAN RESEARCH LTD.
 P.O. BOX 1305
 MARIETTA, GA. 30061

ARA

DATE MFG

DATE TESTED

12-27-77

TYPE GOODS

Centur

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
1	69.4	20	.060	356	28.9	808
2	56.8	20	.060	347	23.7	791
3	55.4	20	.050	337	27.7	772
4	45.1	20	.050	346	22.6	789
5	79.0	20	.070	347	28.2	791
6	57.3	20	.060	393	23.9	877
7	52.1	20	.060	329	21.7	757
8	67.9	20	.065	363	26.1	821

T = F / 2 Wt.

E = 144 + 2D(e)

X 100

106

from 3 Drugstores
Cheng Rai
Samoa 10/75

MAC MILLAN RESEARCH LTD.
P.O. BOX 1305
MARIETTA, GA. 30067

Average Tensile 25.35

Average Elongation 800.75%

Handwritten initials/signature

DATE MFG _____

TYPE GOODS Jr 49

DATE TESTED 12-27-77

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
1	55.0	20	.045	329	30.6	757
2	57.8	20	.050	355	28.9	806
3	47.0	20	.050	328	23.5	755
4	62.0	20	.060	348	25.8	792
5	49.3	20	.050	318	24.7	735
6	70.0	20	.050	369	35.0	832
7	61.6	20	.060	344	25.7	785
8	62.2	20	.050	339	31.1	775
9	50.4	20	.045	356	28.0	808
10	41.9	20	.065	328	16.1	755
11	64.8	20	.070	342	23.1	781
12	57.7	20	.070	338	20.6	774
13	55.2	20	.060	352	23.0	800

$T = \frac{F}{2 \text{ Wt.}}$

$E = \frac{144 + 2D(e)}{106} \times 100$

X 100

106

Atwell Samoa
Oct. '75 mfr date
from two pharmacies / Thailand
RFB

Average Tensile 24.236
Average Elongation 779.14%

MAC MILLAN RESEARCH LTD.
P.O. BOX 1305
MARIETTA, GA. 30061
Alter *AB*

MFG

DATE TESTED 12-27-77

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
14	79.9	20	.070	359	28.5	813
15	56.7	20	.065	339	21.8	775
16	56.5	20	.070	326	20.2	751
17	60.2	20	.060	326	25.1	751
18	47.6	20	.055	330	21.6	758
19	85.9	20	.070	372	30.7	838
20	44.8	20	.065	317	17.2	734
21	41.6	20	.065	296	16.0	694
22	63.7	20	.070	362	22.8	819
23	44.6	20	.060	332	18.6	762
24	75.9	20	.070	370	27.1	834
25	56.5	20	.070	353	20.2	802

$$T = \frac{F}{2 \text{ Wt.}}$$

$$E = 144 + 2D(e)$$

X 100

106

Arnell Samson
Oct. '75
from two Pharmacies

MAC MILLAN RESEARCH LTD,
 P.O. BOX 1335
 MARIETTA, GA. 30067

AKA
ABA

Controlled 100. 7-29-127
TYPE GOODS Couture 52

DATE MFG _____

DATE TESTED 12-28-77

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
1	61.2	20	.050	334	30.5	766
2	69.5	20	.055	379	31.6	851
3	80.6	20	.075	357	26.9	809
4	89.8	20	.075	359	30.0	813
5	74.6	20	.070	368	26.6	830
6	76.1	20	.065	379	29.3	851
7	97.9	20	.075	360	32.6	815
8	63.8	20	.070	343	22.8	783
9	80.1	20	.070	354	28.6	804
10	96.8	20	.065	415	37.2	919
11	63.3	20	.075	350	21.1	796
12	60.8	20	.070	355	20.3	806
13	72.8	20	.060	356	30.3	808

$T = \frac{F}{2 \text{ Wt.}}$

$E = \frac{144 + 2D(e)}{106}$

$\times 100$

106

Tahiti Strips
from ^{PSI PLB} Government Warehouse
In Bangladesh - 9/76 - 10/76 - 11/76 - 8/76

Average Tensile 28.75
Average Elongation 821.32

MAC MILLAN RESEARCH LTD.
P.O. BOX 1305
MARIETTA, GA. 30061
AKA JPA

DATE MFG _____

TYPE GOODS Wires

DATE TESTED 12-28-77

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
14	85.4	20	.070	390	31.0	872
15	83.6	20	.070	395	30.0	881
16	81.9	20	.065	389	32.0	870
17	64.4	20	.060	387	26.8	866
18	84.6	20	.060	372	35.3	838
19	77.9	20	.065	359	30.0	813
20	85.4	20	.070	357	31.0	809
21	105.1	20	.075	363	35.0	821
22	45.6	20	.085	347	13.4	791
23	85.2	20	.060	354	36.0	804
24	53.4	20	.085	328	15.7	755
25	79.5	20	.070	345	28.4	787
26	86.9	20	.085	355	25.6	806

$$T = \frac{F}{2 \cdot Wt.}$$

$$E = 144 + 2D(e)$$

X 100

106

Tahiti Strips
 from Government ^{PSI} Warehouse
 In Bangladesh 9/76 - 10/76 - 11/76 - 8/76

MAC MILLAN RESEARCH LTD.
 P.O. BOX 1305
 MARIETTA, GA. 30061

DATE MFG _____

TYPE GOODS *Case*

DATE TESTED 12-28-77

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
27	55.2	20	.065	336	21.2	770
28	79.7	20	.070	354	28.5	804
29	85.9	20	.060	379	35.8	851
30	68.0	20	.070	352	24.3	810
31	80.2	20	.070	371	28.6	836
32	104.1	20	.075	363	34.7	821
33	69.8	20	.075	373	23.3	840
34	70.9	20	.070	341	25.3	779
35	100.0	20	.080	380	31.3	853
36	75.1	20	.080	369	23.5	832
37	83.8	20	.065	361	32.2	817
38	85.8	20	.075	373	28.6	774
39	72.2	20	.070	343	25.8	783

$T = \frac{F}{2 \text{ Wt.}}$

$E = 144 + 2D(e)$

X 100

106

Tahiti Strips
 from ^{PSI} ~~Government~~ Warehouse
 In Bangladesh - 9/76 - 10/76 - 11/76 - 8/76

MAC MILLAN RESEARCH LTD.
 P.O. BOX 1305
 MARIETTA, GA. 30061

Handwritten initials

DATE MFG _____

TYPE GOODS Con

DATE TESTED 12-28-77

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
40	99.5	20	.080	367	31.1	828
41	81.1	20	.070	432	29.0	951
42	87.1	20	.065	378	33.5	849
43	85.5	20	.060	380	35.6	853
44	71.5	20	.070	366	25.5	826
45	82.5	20	.070	373	29.5	848
46	64.5	20	.070	337	23.0	772
47	58.4	20	.070	337	20.9	772
48	82.4	20	.070	358	29.4	811
49	72.4	20	.065	368	27.8	830
50	93.8	20	.065	389	36.1	870

$$T = \frac{F}{2 \text{ Wt.}}$$

$$E = \frac{144 + 2D(e)}{106}$$

$$X = 100$$

106

MAC MILLAN RESEARCH LTD.
P.O. BOX 1305
MARIETTA, GA. 30061
Just

Serial position: 115-27-124

DATE MFG _____

TYPE GOODS Culture

DATE TESTED 12-28-77

49

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
1	97.0	20	.070	388	34.6	868
2	73.8	20	.075	354	25.0	804
3	80.8	20	.065	368	31.1	830
4	86.6	20	.070	361	31.0	817
5	107.6	20	.060	384	44.8	860
6	92.1	20	.060	352	38.4	808
7	87.9	20	.070	375	31.4	843
8	53.0	20	.060	335	22.1	768
9	82.7	20	.070	361	30.0	817
10	80.5	20	.065	366	31.0	826
11	79.3	20	.065	376	31.0	845
12	57.9	20	.065	331	22.3	760
13	80.3	20	.070	354	28.7	804

$T = \frac{F}{2 \text{ Wt.}}$

$E = 144 + 2D(e)$

X 100

106

*Sabiti Strips, Borneo,
from Thailand, from
CBFPS Public
Government Warehouse.*

5/75 4/75

*Average Tensile 28.528
Average Elongation 810.8%*

MAC MILLAN RESEARCH LTD.
P.O. BOX 1305
MARIETTA, GA. 30061

DATE MFG _____

DATE TESTED 12-28-77

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
14	69.7	20	.065	337	26.8	772
15	64.9	20	.060	334	27.0	776
16	69.9	20	.065	347	26.9	791
17	69.3	20	.060	360	28.9	815
18	52.9	20	.060	328	22.0	755
19	61.0	20	.060	355	25.4	806
20	75.9	20	.070	340	27.1	777
21	70.9	20	.060	350	30.0	796
22	51.2	20	.060	326	21.3	751
23	76.7	20	.060	338	32.0	774
24	68.8	20	.065	337	26.5	772
25	70.7	20	.070	337	25.3	772
26	55.2	20	.065	348	21.2	792

$$T = \frac{F}{2 Wt.}$$

$$E = \frac{144 + 2D(e)}{100}$$

$$X \quad 100$$

106

ERIC WILLIAM RESEARCH LTD.
P.O. BOX 1305
MARIETTA, GA. 30061

JGA

DATE MFG _____

DATE TESTED 12-28-77

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
27	70.9	20	.065	345	27.3	787
28	73.4	20	.060	395	30.6	881
29	75.1	20	.075	365	25.0	825
30	73.8	20	.055	343	33.5	877
31	63.6	20	.060	338	27.0	774
32	84.2	20	.065	350	32.4	796
33	73.1	20	.065	357	28.1	809
34	82.8	20	.060	357	35.0	809
35	68.7	20	.060	370	28.6	834
36	85.3	20	.070	360	30.5	815
37	74.3	20	.070	392	27.0	875
38	72.8	20	.065	355	28.0	806
39	70.6	20	.070	347	25.2	791

$$T = \frac{F}{2 \text{ Wt.}}$$

$$E = 144 + 2D(e)$$

$$\times 100$$

106

MAC MILLAN RESEARCH L
P.O. BOX 1305
MARIETTA, GA. 30067

DATE MFG _____

TYPE GOODS Concrete

DATE TESTED 12-28-77

49

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
40	93.5	20	.075	388	31.2	868
41	57.4	20	.065	331	22.1	760
42	70.5	20	.060	361	29.4	817
43	79.3	20	.061	376	33.0	845
44	73.8	20	.070	346	26.4	789
45	90.9	20	.075	381	30.3	855
46	89.1	20	.080	392	27.8	875
47	86.8	20	.065	386	33.4	864
48	57.2	20	.065	329	22.0	757
49	73.7	20	.070	378	26.3	849
50	58.9	20	.060	343	24.5	783

$$T = \frac{F}{2 \text{ Wt.}}$$

$$E = \frac{144 + 2D(e)}{106}$$

$$X = 100$$

106

MAC MILLAN RESEARCH
 P.O. BOX 1305
 MARIETTA, GA. 30061

Handwritten initials/signature

DATE MFG _____

- 69 -

Order No: 11-27-77

TYPE GOODS Cantures

DATE TESTED 12-27-77

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
1	83.8	20	.060	360	34.9	815
2	68.6	20	.060	366	28.6	826
3	71.1	20	.060	329	29.6	757
4	71.9	20	.060	360	30.0	815
5	92.8	20	.070	366	33.1	826
6	64.6	20	.060	354	26.9	804

$T = \frac{F}{2 \text{ Wt.}}$

$E = \frac{144 + 2D(e)}{106} \times 100$

X 100

106

From 3 Druggstores
Chiang Rai
Jahuti Strip 6/75

MAC MILLAN RESEARCH LTD.

P.O. BOX 1305

MARIETTA, GA. 30061

Average Tensile 30.52
Average Elongation 807.17%

[Handwritten initials]

DATE MFG _____

TYPE GOODS Curtain

DATE TESTED 12-27-77

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
1	72.8	20	.060	364	30.3	823
2	63.9	20	.070	351	22.8	798
3	86.2	20	.070	369	30.8	832
4	90.9	20	.065	365	35.0	825
5	88.6	20	.060	374	36.9	842
6	78.4	20	.060	360	32.7	815
7	60.1	20	.060	351	25.0	798
8	69.0	20	.060	374	28.8	842
9	71.0	20	.070	360	25.4 29.6	815
10	56.7	20	.060	345	23.6	787
11	61.4	20	.065	324	23.6	747
12	89.0	20	.060	393	32.1	877
13	89.9	20	.065	375	34.6	843

$T = \frac{F}{2 \text{ Wt.}}$

$E = 144 + 2D(e)$

$\times 100$

106

from 3 Drugstores
Cheng Rai

Joheti Rainbow test date 6/75

Average Tensile 29.75
Average Elongation 827.18%

MAC MILLAN RESEARCH LTD.
P.O. BOX 1305
MARIETTA, GA. 30067

Handwritten signatures and initials

DATE MFG _____

TYPE GOODS Concrete 49

DATE TESTED 12-28-77

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
1	89.2	20	.065	372	34.3	838
2	58.6	20	.055	356	26.6	808
3	65.4	20	.070	332	23.4	762
4	75.3	20	.075	351	25.1	798
5	64.0	20	.070	362	22.9	819
6	63.2	20	.080	327	19.8	753
7	70.5	20	.065	375	27.1	843
8	60.6	20	.060	361	25.3	817
9	66.2	20	.060	370	22.6	834

$T = \frac{F}{2 \text{ Wt.}}$

$E = \frac{144 + 2D(e)}{106} \times 100$

X 100

106

Purchases
In Chiang Rai
Rural Program
Jahiti Strips - 6-75

MAC MILLAN RESEARCH LTD
P.O. BOX 1305
MARIETTA, GA. 30061

Average Tensile 25.79

Average Elongation 808%

DATE MFG _____

TYPE GOODS Couture

DATE TESTED 12-28-77

49

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
1	60.4	20	.065	329	23.2	757
2	63.9	20	.060	354	26.6	804
3	75.6	20	.070	363	27.0	821
4	69.3	20	.065	357	26.7	809
5	76.5	20	.070	347	27.3	791
6	74.2	20	.065	361	28.5	817
7	75.3	20	.060	339	31.4	775
8	59.7	20	.070	328	21.3	755
9	70.6	20	.060	344	29.4	785
10	70.5	20	.060	360	29.4	819
11	67.5	20	.065	352	26.0	800
12	73.6	20	.060	364	30.1	823

$T = \frac{F}{2 \text{ Wt.}}$

$E = 144 + 2D(e)$

X 100

106

Purchases In
Cheung Kai
Rural Program

ANTI-Rainbow 5/75

MAC MILLAN RESEARCH LTD.

P.O. BOX 1305
MARIETTA, GA. 30061

[Handwritten signatures]

Average Tensile 32.29
Average Elongation 796.33 %

DATE MFG _____

TYPE GOODS Carton

DATE TESTED 12-27-77

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
1	102.3	20	.070	382	36.5	857
2	86.0	20	.065	374	33.1	842
3	78.6	20	.070	373	28.1	840
4	69.6	20	.060	363	29.0	821
5	108.6	20	.070	383	38.8	858
6	57.0	20	.060	324	23.8	747
7	62.5	20	.065	338	24.0	774
8	65.1	20	.065	365	25.0	825
9	77.2	20	.070	351	22.6	798
10	76.5	20	.050	354	38.3	804
11	77.1	20	.065	373	29.7	840
12	39.8	20	.065	312	15.3	725
13	66.4	20	.065	366	25.5	826

$T = \frac{F}{2 \text{ Wt.}}$

$E = \frac{144 + 2D(e)}{106}$

$\times 100$

106

3794 L in strips for village programs

June 75

from 80 gross Carton (partially used) in Chiang Rai since Sept. 76

from CBFBS - Warehouse Chiang Rai

Average Tensile 28.212

MAC MILLAN RESEARCH LTD.
P.O. BOX 1385
BANGKOK

DATE MFG _____

TYPE GOODS Centire

DATE TESTED 12-27-77

DAILY TENSILE AND ELONGATION TEST

Sample #	F(n)	W(mm)	t(mm)	D(e)	T(MPa)	E(%)
14	55.6	20	.060	338	23.2	774
15	55.4	20	.060	318	23.1	736
16	68.0	20	.070	343	24.3	783
17	65.0	20	.060	305	22.1	711
18	54.0	20	.060	334	22.5	766
19	87.7	20	.070	394	31.3	879
20	74.3	20	.060	360	31.0	815
21	75.4	20	.065	384	29.0	860
22	60.3	20	.065	333	23.2	764
23	97.7	20	.070	376	31.3	845
24	82.0	20	.070	374	29.3	842
25	84.8	20	.060	373	35.3	840

$$T = \frac{F}{2 \text{ Wt.}}$$

$$E = \frac{144 + 2D(e)}{100}$$

X 100

106

MAC MILLAN RESEARCH LTD.
 P.O. BOX 1305
 MARIETTA, GA. 30067
JFA *JFA*

Rec'd 11/16/77

ZZ-C-001597A(GSA-FSS)

September 19, 1977

SUPERSEDING

ZZ-C-001597(GSA-FSS)

February 10, 1970

INTERIM FEDERAL SPECIFICATION

CONDOMS, RUBBER CONTRACEPTIVE

This Interim Federal Specification was developed by the General Services Administration, Federal Supply Service, Washington, DC 20406, based upon currently available technical information. It is recommended that Federal agencies use it in procurement and forward recommendations for changes to the preparing activity at the address shown above.

1. SCOPE AND CLASSIFICATION

1.1 Scope. This specification covers the requirements for natural rubber contraceptive condoms.

1.2 Classification. Condoms covered by this specification shall be the following types, styles, classes, and sizes, as specified (sec 6.2).

Type I - Noncontoured

Type II - Contoured (style B, only; see 3.2.1)

Style A - Round End

Style B - Reservoir End

Class A - Nonlubricated (powdered)

Class B - Lubricated

Size 1 (large) - 180 ± 10 mm in length

Size 2 (small) - 160 ± 10 mm in length

2. APPLICABLE DOCUMENTS

2.1 The following documents, of the issues in effect on date of invitation for bids or request for proposal, form a part of this specification to the extent specified herein.

Federal Standards:

Fed. Std. No. 123 - Marking for Shipment (Civil Agencies)

(Activities outside the Federal Government may obtain copies of Federal Specifications, Standards, and Handbooks as outlined under General Information in the Index of Federal Specifications and Standards and at the prices indicated in the Index. The Index, which includes cumulative monthly supplements as issued, is for sale on a subscription basis by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

(Single copies of this specification and other Federal Specifications required by activities outside the Federal Government for bidding purposes are available without charge from Business Service Centers at the General Services Administration Regional Offices in Boston, New York, Washington, DC, Atlanta, Chicago, Kansas City, MO, Fort Worth, Denver, San Francisco, Los Angeles, Seattle, WA.

(Federal Government activities may obtain copies of Federal Specifications, Standards, and Handbooks and the Index of Federal Specifications and Standards from established distribution points in their agencies.)

Military Standards:

MIL-STD-105 - Sampling Procedures and Tables for Inspection
by Attributes

(Copies of Military Specifications and Standards required by suppliers in connection with specific procurement functions should be obtained from the procuring activity or as directed by the contracting officer.)

2.2 Other publications. The following documents form a part of this specification to the extent specified herein. Unless a specific issue is identified, the issue in effect on date of invitation for bids or request for proposal shall apply.

Navy
(215)
697-3321

American Society for Testing and Materials (ASTM) Standards:

D 3492 - Rubber Contraceptives (Condoms), Standard
Specification for

(Application for copies should be made to the American Society
for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.)

National Motor Freight Traffic Association, Inc., Agent:

National Motor Freight Classification.

(Application for copies should be addressed to the American Trucking
Associations, Inc., Traffic Department, 1616 P Street, N.W., Washington,
DC 20036.)

Uniform Freight Classification.

(Application for copies should be addressed to the Uniform Classification
Committee, Room 1106, 222 South Riverside Plaza, Chicago, IL 60606.)

Laws and Regulations:

21 CFR 1 - The Federal Food, Drug, and Cosmetic Act and
the Fair Packaging and Labeling Act and
regulations promulgated thereunder.

(The Code of Federal Regulations (CFR) and the Federal Register (FR)
are for sale on a subscription basis by the Superintendent of Documents,
U.S. Government Printing Office, Washington, DC 20402. When indicated,
reprints of certain regulations may be obtained from the Federal agency
responsible for issuance thereof).

3. REQUIREMENTS

3.1 Materials.

3.1.1 Latex. Condoms shall be made of natural rubber latex, and shall be
capable of meeting all requirements and passing all tests specified herein.
The rubber latex used shall be free of embedded grit and discoloration.
Condoms shall be transparent and either clear (i. e. natural colored) or
colored, as specified (see 6.2). Colored condoms shall be available in the
following manufacturer's standard colors: Red, Blue, Green, Pink, Black,
and Yellow, as specified (see 6.2). The condoms shall not liberate toxic or
otherwise harmful substances under normal conditions of use, and shall be
in strict compliance with the applicable portions of 21 CFR 1 (see 4.4.8).

ZZ-C-001597A

3.1.2 Dressing and compounding materials. Dressing materials (e.g. powders, lubricants, etc.) and compounding materials (coloring agents and other additives) shall not have a deleterious effect on the condoms, nor shall they have a harmful or irritating effect on the human body. Such materials shall be in strict compliance with the applicable portions of 21 CFR 1 (see 4.4.8)..

3.2 Construction. Condoms shall consists of smooth surfaced, essentially cylindrical, latex sheaths with one open end. The open end shall have a thin ring consisting of several layers of latex contiguous with the sheath. When tested as specified in 4.4.4, condoms shall have a maximum weight of 1.70 grams. When tested as specified in 4.4.2.1, condoms shall have an average wall thickness of from 0.040 mm (min.) to 0.070 mm (max.), and no individual wall thickness measurement shall exceed 0.090 mm.

3.2.1 Type I and Type II. Type I condoms shall be straight, without constrictions. The closed end of Type I condoms may be straight or expanded, according to the manufacturer's standard practice. Type II condoms shall have a formfitting profile, consisting of an essentially cylindrical sheath for one-half to two-thirds of its length (measured from the open end), followed by a constricted portion, followed in turn by an expanded portion, and in all cases, terminating with a definite shoulder and reservoir tip (style B, only; see 1.2); when condoms are tested as specified in 4.4.2.2, the laid flat width of the expanded portion (at its maximum) shall never be less than the laid flat width of the "shank."

3.2.2 Style A and Style B. Style A condoms shall have a smoothly rounded tip, without additional features. The closed end of Style B condoms shall have a visible shoulder leading to a reservoir pouch at the tip.

3.2.3 Length and width. When condoms are tested as specified in 4.4.2.2, their lengths shall be as specified in 1.2; their widths shall be as specified in Table I.

TABLE I. Laid Flat Width Requirements

Classification	Point of Measurement (i. e. distance from the open end.)	Width
Type I:		
Size 1	80 \pm 5 mm	52 \pm 3 mm
Size 2	80 \pm 5 mm	49 \pm 2 mm
Type II:		
Size 1	80 \pm 5 mm	52 \pm 3 mm
	130 \pm 15 mm	35 \pm 5 mm
Size 2	80 \pm 5 mm	49 \pm 2 mm
	110 \pm 15 mm	35 \pm 5 mm

3.3 Class A and Class B condoms. Class A condoms shall be powdered to prevent the latex from sticking to itself, and to facilitate mechanical manipulation of the condoms. Class B condoms shall be dressed with a water based jelly or silicone oil type lubricant, as specified (see 6.2). When Class B condoms are tested as specified in 4.4.3, the amount(s) of lubricant used shall be as follows:

- water-base jelly type - 350 mg (min.) to 550 mg (max.)
- silicone oil type - 250 mg (min.) to 500 mg (max.)

Powders and lubricants shall be applied directly to the condoms in accordance with the manufacturer's standard practice. Powders and lubricants shall be as specified in 3.1.2.

3.4 Tensile strength and elongation. When tested as specified in 4.4.5, the tensile strength and elongation at break characteristics of the condoms shall be as specified in Section 6 of ASTM D3492.

3.5 Pinholes. Condoms shall show no evidence of pinholes when tested by an electronic testing machine, as specified in 4.4.6.

3.6 Water leakage. Condoms shall show no evidence of water leakage when tested as specified in 4.4.7.

ZZ-C-001597A

3.7 Identification marking. Each individual condom shall have the manufacturer's name or symbol and the date (i. e. month/year) of manufacture imprinted on the condom, near the open end.

3.8 Workmanship. The workmanship shall be first class throughout. Condoms shall be free of defects which affect their durability, detract from their appearance, or which may impair their serviceability.

4. QUALITY ASSURANCE PROVISIONS

4.1 Responsibility for inspection. Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or order, the supplier may use his own or any other facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the Specification where such inspections are deemed necessary to assure that supplies and services conform to prescribed requirements.

4.2 Objective evidence. The supplier shall provide objective evidence acceptable to the contracting officer that the requirements of 3. 1. 1 and 3. 1. 2, for which specific inspection has not been provided, have been satisfied (see 4. 4. 8).

4.3 Sampling. Sampling plans in tables II and III for the water leakage test are matched to certain plans in MIL-STD-105. The normal, tightened, and reduced inspection provisions of MIL-STD-105 may be used, as applicable, as sampling plans in this specification.

4.4 Examination and tests.

4.4.1 Visual examination. A visual examination for defects in materials, construction, and workmanship shall be performed on condoms selected for the water leakage test (see 4. 4. 7). Sample sizes and acceptance/rejection (Ac/Rc) numbers, expressed in terms of percent defective, shall be identical to those specified in table II. The presence of one or more imperfections in material, etc., in the same condom shall constitute a defective condom. Results of the visual examination shall be kept separately from the results of the tests.

4.4.2 Dimensions. Five condoms shall be selected at random from each lot for determination of compliance with the applicable thickness, and length and width requirements of 3.2, 3.2.1, 3.2.3, and table I. Wall thickness measurements shall be made on condoms from which all dressing materials have been removed with water or isopropanol and then dried to a constant mass. The acceptance number for dimensional tests shall be zero (i. e. any evidence of noncompliance with specified requirements shall be cause for rejection of the lot.).

4.4.2.1 Wall thickness. The wall thickness of condoms shall be measured at three points, 10 ± 2 mm from the open end, 30 ± 5 mm from the closed end, and at the mid-distance between those two points. Lateral measurements made from the closed end of style B condoms shall exclude the reservoir tip. The individual measurements and the average value of all three measurements shall be recorded for each condom.

4.4.2.2 Length and width. Measurement of condom length shall be made from the open end to the furthest extension of the closed end (exclusive of the reservoir tip on style B condoms). Width measurements shall be made on laid flat condoms. Width measurements shall be taken at the points specified in table I. The expanded portion of type II condoms shall be inspected to assure compliance with the applicable requirements of 3.2.1.

4.4.3 Quantity of lubricant. Twenty individual condoms, selected at random from each lot shall be tested for compliance with the quantity of lubricant requirements of 3.3, as applicable. The test procedure(s) shall be as follows:

(a) water-based lubricant; lubricated condoms, sealed in their individual packets, shall be weighed on an analytical balance. Each packet shall be opened taking care to retain all pieces thereof. The packet and condom shall be washed in denatured ethanol until all lubricant is removed, dried to a constant mass, and then weighed again; the condom without its packet shall also be weighed. All weights shall be recorded to the nearest milligram (mg). Compliance with the requirements of 3.3 shall be determined by subtracting the weight of the washed and dried sample (packet and condom) from the initial weight of the sample prior to removal of the lubricant.

(b) silicone oil lubricant; this procedure shall be identical to that specified in (a), except that the condom packet shall be discarded prior to the initial weighing and shall not be used in any of the procedural steps; i. e., only the lubricated condom shall be used in this procedure.

4.4.3 In both (a) and (b), all procedural steps shall be completed for each sample before proceeding to subsequent samples. The acceptance number for this test shall be zero.

Individual condom weights recorded in (a) and (b), as applicable, shall be used to satisfy the requirements of 4.4.4.

4.4.4 Weight. The twenty condoms tested as specified in 4.4.3, from which all dressing materials have been removed, shall be dried to a constant mass and then weighed on an analytical balance to determine compliance with the applicable requirements of 3.2. The acceptance number for this test shall be zero.

4.4.5 Tensile strength and elongation test. Sample condoms shall be selected and tested as specified in Section 6 of ASTM D3492. The compliance and acceptance criterion shall be as specified therein.

4.4.6 Pinhole test. The test for pinholes shall be performed on a 100 percent basis (i. e. no sampling). The electronic testing shall be performed by utilizing an electronically charged liquid bath (wet method), or a gammeter test (dry method) which examines the product dry. Condoms failing to meet the requirements of 3.5 shall be removed.

4.4.7 Water leakage test. After the pinhole test specified in 4.4.6, and prior to shipment, condoms shall be sampled and inspected in accordance with tables II and III, as applicable. Sample condoms shall be placed in a funnel rack approximately twelve (12) inches above the base support, and each condom shall then be filled with 300 cubic centimeters (ml) of water. The open end of the condom(s) shall then be closed by squeezing the beaded portion together. The filled condom(s) shall be laid on a piece of dry filter paper, rolled from side to side, and examined for water leakage in compliance with 3.6. Lot acceptability shall be based upon the acceptance (Ac) and rejection (Re) numbers (representing defective condoms) in tables II and III, as applicable.

Table II. Sampling Plans for Water Leakage Test *, and for Visual Examination (see 4.4.1).

*Area of examination: Between 25 mm from the open end and the closed end.

Lot size 35,000 and less

Type of Sampling Plan	Cumulative Sample Size	Ac	Re
Single	500	2	3
Double	315	0	3
	630	3	4
Multiple	125	#	2
	250	0	3
	375	0	3
	500	1	4
	625	2	4
	750	3	5
	875	4	5

Lot size 35,001 - 150,000

Single	800	5	6
Double	500	2	5
	1000	6	7
Multiple	200	#	4
	400	1	5
	600	2	6
	800	3	7
	1000	5	8
	1200	7	9
	1400	9	10

Table II continued

Lot size 150,001 - 500,000

Type of Sampling Plan	Cumulative Sample Size	Ac	Re
Single	1250	7	8
Double	800	3	7
	1600	8	9
Multiple	315	0	4
	630	1	6
	945	3	8
	1260	5	10
	1575	7	11
	1890	10	12
	2205	13	14

Lot size 500,001 and over

Single	2000	14	15
Double	1250	7	11
	2500	18	19
Multiple	500	1	7
	1000	4	10
	1500	8	13
	2000	12	17
	2500	17	20
	3000	21	23
	3500	25	26

Table III. Sampling Plan for Water Leakage Test in the area between the open end, and 25 mm from the open end. This plan is applicable to all lot sizes.

Type of Sampling Plan	Cumulative Sample Size	Ac	Re
Single	500	21	22
Double	315	11	16
	630	26	27
Multiple	125	2	9
	250	7	14
	375	13	19
	500	19	25
	625	25	29
	750	31	33
	875	37	38

4.4.8 Added materials. Contractors shall provide adequate certification that the condoms, all dressing materials (powders, lubricants, etc.), and all compounding materials (coloring agents and other additives) are in compliance with the applicable portions of 21 CFR 1, and that they have been tested in accordance with applicable Food and Drug Administration regulations in force at the time of the manufacture of the condoms.

4.5 Inspection of preparation for delivery. An inspection shall be performed to insure that packaging, packing, and marking are in compliance with the requirements of Section 5. The inspection shall be conducted in accordance with MIL-STD-105. The lot size shall be the number of shipping containers and interior packages in the end item inspection lot. The inspection level shall be S-3, with an Acceptable Quality Level (AQL) of 2.5, expressed in terms of percent defective. For the purpose of exterior packing examination, the sample unit shall be one shipping container; for interior packaging examination, the sample unit shall be one package. Examination of interior packaging shall be performed on packages selected at random from sample shipping containers. Examination of defects of closure shall be performed on randomly selected shipping containers, fully prepared for delivery. Preparation for delivery defects shall be scored in accordance with table IV.

Table IV. Classification of Preparation for Delivery Defects

Examine	Defects
Contents	Number of condoms not as specified; packets or strips not as specified.
Marking (Exterior and Interior)	Omitted; incorrect; illegible; of improper size, location, sequence, or method of application.
Materials	Packaging/packing materials not as specified, missing, damaged, or nonserviceable.
Workmanship	Containers inadequately closed and secured, poor application or internal packaging and packing material; distorted intermediate packages.

5. PREPARATION FOR DELIVERY

5.1 Packaging. Packaging shall be level A or commercial, as specified (see 6.2).

5.1.1 Level A. Condoms shall be sealed in individual packets constructed of a suitable flexible metal foil, plastic film, or combination thereof. The sealed packets shall be provided in strips of three or four, separated by perforations to facilitate detachment. When colored condoms are specified in the contract or order, the sealed packets shall consist in part of transparent plastic film through which the color of the condom can be identified. One gross (144) of condoms shall be neatly packaged in a folding or set-up paperboard box.

5.1.2 Commercial. Condoms shall be preserved and packaged in accordance with normal commercial practice. The complete package shall be designed to protect the condoms against damage during shipment, handling, and storage.

5.2 Packing. Packing shall be level A or commercial, as specified (see 6.2).

5.2.1 Level A. Condoms, packaged as specified in 5.1.1, shall be packed in corrugated fiberboard boxes made from Weather-Resistant fiberboard with a bursting test strength of not less than 275 pounds per square inch. The box flaps shall be secured with water resistant adhesive applied to not less than 75 percent of the area of contact between the flaps or with 3 inch wide water resistant tape applied to the full length of the center seams and extending over the ends not less than 3 inches. Alternatively, wirebound, cleated plywood, or nailed wood boxes shall be acceptable shipping containers when lined with a waterproof barrier material. The barrier material shall be sealed at the edges with waterproof tape or adhesive.

5.2.2 Commercial. Condoms, packaged as specified in 5.1.2, shall be packed in fiberboard boxes to insure safe delivery at destination, to provide for safe redistribution by the initial receiving activity, and shall be acceptable by common carrier under National Motor Freight Classification or Uniform Freight Classification.

5.3 Unitization. When shipments to Government depots are full car or truckload, the shipping containers shall be unitized for shipment and handling in accordance with normal commercial practice. The unitized load shall not exceed 2,500 pounds in weight, 63 inches in height, 56 inches in length, and 45 inches in width.

5.4 Marking. In addition to markings required by the contract or order, packages, shipping containers, and unitized loads (when applicable) shall be marked in accordance with Fed. Std. No. 123.

6. NOTES

6.1 Intended use. Condoms covered by this specification are intended for use as contraceptive and prophylactic agents.

6.2 Ordering data. Purchasers should select the preferred options permitted herein, and include the following information in procurement documents.

- (a) Title, number, and date of this specification.
- (b) Type, style, class, and size condom required (see 1.2).
- (c) Whether clear (natural colored) or colored condoms are required (see 3.1.1); if colored condoms are required, what colors are required (see 3.1.1).
- (d) Whether the water-based or silicone oil type lubricant is required (see 3.3).
- (e) Selection of applicable levels of packaging and packing (see 5.1 and 5.2).
- (f) Unitization required (see 5.3).
- (g) Marking required (see 5.4).

6.3 Definitions. The following terms, as used in this specification shall be defined as indicated.

laid flat width: one half of the circumference (of the condom) at the designated point.

shank: that portion of the condom lying between the open end and the first visible constriction, convolution or contour, etc., (see 3.3).

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PART 38

Rubber Products, Industrial—Specifications
and Related Test Methods;
Gaskets; Tires

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AMERICAN SOCIETY FOR TESTING AND MATERIALS
1916 Race St., Philadelphia, Pa. 19103



Designation: D 3492 - 76

Standard Specification for RUBBER CONTRACEPTIVES (CONDOMS)¹

This Standard is issued under the fixed designation D 3492; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reappraisal.

1. Scope

1.1 This specification covers requirements for condoms made of rubber latex intended for single use. The scope of the specification does not cover spermicidal or other dressing materials that may be applied to condoms.

1.2 This specification is intended to serve as a guide to permit obtaining condoms of consistent performance. The safe and proper use of condoms is excluded from the scope of this specification.

2. Applicable Documents

2.1 ASTM Standards:

D 412 Tests for Rubber Properties in Tension²

D 573 Test for Rubber Deterioration in an Air Oven²

D 865 Test for Rubber Deterioration by Heating in a Test Tube²

D 1076 Specification for Rubber—Concentrated, Ammonia Preserved, Creamed and Centrifuged Natural Latex²

2.2 Other Documents:

ISO 2859 Sampling Procedures and Tables for Inspection by Attributes³

Code of Federal Regulations, Title 21—Food and Drugs⁴

3. Classification

3.1 Condoms covered by this specification shall be of the following types and classes:

Standard I—approximately 52 mm width.

Standard II—approximately 49 mm width.

Type I—smooth surface.

Type II—textured surface.

Form I—round end.

Form II—reservoir end.

Form III—form fitting.

Class A—dry.

Class B—lubricated.

4. Materials

4.1 Condoms shall be manufactured from good quality natural rubber latex conforming to Specification D 1076, and shall be free of embedded grit or discoloration. Condoms may be transparent, translucent, opaque, or colored.

4.2 The condoms and any dressing material applied to them shall not liberate substances that are known to be toxic or otherwise harmful under normal conditions of use. Any dressing materials, or compounding materials shall not have a deleterious effect on the condom. Materials used should be permitted by code of Federal Regulations Title 21, Part 121, Subparts E and F, which list materials safe for use in food packaging.

5. Design

5.1 *Rim*—The open end of the condom shall terminate in an integral rim.

5.2 *Dimensions*—From each lot or batch (not to exceed 144 000 pieces), ten condoms shall be drawn at random. Those condoms tested shall meet the requirements in Table 1.

¹ This specification is under the jurisdiction of ASTM Committee D-11 on Rubber and Rubber-Like Materials, and is the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

Current edition approved March 26, 1976. Published May 1976.

² Annual Book of ASTM Standards, Part 37.

³ Available from American National Standards Institute, 1430 Broadway, New York, N. Y. 10018.

⁴ Available from the Superintendent of Documents, U. S. Government Printing Office, Washington, D. C. 20407.

If any one fails to meet these requirements, the lot or batch shall be rejected.

5.2.1 For Standard I, Form III condoms having a shaped profile about the closed end, the width of the profile, when laid flat, shall be not more than 70 mm.

5.2.2 For Standard II, Form III condoms, the width in 5.2.1 shall be not more than 62 mm.

5.3 Procedures for Dimensional Test:

5.3.1 The length of the condom excluding the teat shall be measured to the nearest 1 mm.

5.3.2 The width of the condom laid flat shall be measured at a distance greater than 85 mm from the rim. The measurement shall be reported to the nearest 0.5 mm.

5.3.3 The thickness shall be measured on condoms from which lubricant has been removed with water or isopropanol and then dried to constant mass. The micrometer shall conform to that specified in Method D 412. When a condom is textured, the thickness shall be measured in a nontextured area. The measurements shall be reported to the nearest 0.01 mm.

5.3.4 The mass of a condom after the thickness measurement shall be measured on a balance and reported to the nearest 1 mg.

6. Physical Requirements

6.1 Tensile Strength and Elongation at Break.—The tensile strength and elongation at break shall comply with the following requirements:

	Tensile Strength, min. MPa		Elongation at Break %, min %	
	mean	specimen	mean	specimen
Samples tested less than 12 months after manufacture in the as-sampled condition	20	15	750	675
Sample tested less than 12 months after manufacture and subjected to accelerated aging	17	15	700	625
Sample tested 12 months or more after manufacture in the as-sampled condition	17	15	700	625

From each lot or batch (not to exceed 144 000 pieces), 25 condoms shall be drawn at random for each test. The condoms tested should meet or exceed the appropriate mean values in the table, and if more than 1 out of 25 values for individual specimens falls below specimen values listed, the lot shall be rejected.

6.2 Determination of Tensile Properties:

6.2.1 Conditioning—Determine the tensile strength and elongation at break of 25 condoms after aging for 166 ± 2 h at $70 \pm 2^\circ\text{C}$, in accordance with Methods D 573 or D 865. If Method D 573 is used, do not age condoms of different composition simultaneously in the same oven. Age condoms as received in original packages. After aging, condition condoms at $23 \pm 2^\circ\text{C}$ for not less than 16 h and prepare and test specimens as described in 6.2.2 within 96 h.

6.2.2 Procedure—Determine tensile strength and elongation at break of 25 condoms in accordance with Method D 412 using ring specimens as follows:

6.2.2.1 Cut the specimens perpendicular to the length direction of condom with a die having cutting edges 20.0 ± 0.1 mm apart and at least 70 mm long. Cut the specimens in the region of the condom about 80 mm from the rim. In textured condoms, cut the specimen from the nontextured region. Use only specimens cut by a single impact of the die.

6.2.2.2 Measure the thickness of three or more equidistant points around the ring to the nearest 0.001 mm and record the median value for the thickness.

6.2.2.3 Dust the specimen, lay the ring flat, and measure the distance between the two folded edges. Multiply the measurement by two to obtain the circumference of the ring.

6.2.2.4 Test the specimen to failure in a tester having a range of about 100 N at a speed of 8.5 ± 0.8 mm/s. Use roller grips at least 20 mm in width, between 5 and 15 mm in diameter, and lubricated on surfaces contacting the specimen with castor oil or other effective rubber lubricant. Record the force and grip separation at break.

6.2.3 Calculations:

6.2.3.1 Calculate the tensile strength as follows:

$$T = F/2WD$$

where:



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- T* = tensile strength, MPa.
- F* = breaking force, N.
- W* = width of ring, 20 mm, and
- D* = single thickness of wall, mm.

6.2.3.2 Calculate the elongation at break as follows:

$$E = 100 [(2D + G - C)/C]$$

where:

- E* = elongation at break, %,
- D* = distance between centers of the rollers at break, mm,
- G* = circumference of one roller, mm, and
- C* = circumference of the specimen, mm.

7. Quality Assurance

7.1 *Responsibility for Inspection*—Unless otherwise indicated, the supplier is responsible for the performance of all inspection requirements.

7.2 Leakage:

7.2.1 *Sampling*—Inspection for leakage shall follow ISO 2859, General Inspection Level I for an acceptable quality level (AQL) of 0.4 %. Single, double, and multiple sampling plans for normal inspection are given in Table 2 for four ranges of lot sizes. Multiple sampling is preferable and shall be used in reference tests.

7.2.2 *Procedure*—Fill each condom in the sample with 300 cm³ of water. Twist rim end to form a seal. Wipe outside surface dry by rolling on filter paper or equivalent absorbant material. Inspect for holes. Reject lots of condoms that are too small to hold 300 cm³ of water or which have a number of leaks equaling or exceeding the appropriate rejection

number in Table 2.

8. Marking

8.1 *Condom Identification*—Each condom must be legibly marked to include the name or trademark of the manufacturer and the date (month and year) of manufacture, coded or explicit.

8.2 *Package Identification*—Packaging shall have the name and address of the manufacturer or distributor, and the country of manufacture.

9. Packaging and Storage

9.1 Unless otherwise specified, packaging shall be in accordance with manufacturer's commercial practice.

9.2 Proper packaging should protect condoms during storage for 10 years or more. Nevertheless, condoms should not be kept in storage longer than necessary, especially in warm climates, and should be stored in a cool place in containers that protect them from mechanical damage.

9.3 Condoms shall not be allowed to come into contact with oil-based antiseptics, phenols and their derivatives, petroleum-based products, or other materials harmful to rubber.

10. Retest

10.1 One retest for design and requirements is permissible before final rejection of lots not conforming to Sections 5 and 6.

10.2 No retest is permitted for lots not conforming to Section 7.

TABLE 1 Dimensional Requirements

	Length, mm	Width, mm	Thickness, mm	Mass, g., max
Standard I, Type I	180 ± 10	52 ± 3	0.04 ± 0.09	1.70
Standard II, Type I	160 ± 10	49 ± 2	0.04 ± 0.07	1.50
Standard I, Type II	180 ± 10	52 ± 3	0.04 ± 0.09	1.95
Standard II, Type II	160 ± 10	49 ± 2	0.04 ± 0.09	1.75

TABLE 2 Normal Inspection Sampling Plans for Water Leakage Test^a

Lot Size 35 000 and less				Lot Size 35 001 to 150 000			
Type of Sampling Plan ^b	Cumulative Sample Size	AC ^c	RE ^c	Type of Sampling Plan ^b	Cumulative Sample Size	AC ^c	RE ^c
Single (IIA,K)	125	1	2	Single (IIA,L)	200	2	3
Double (IIIA,K)	80	0	2	Double (IIIA,L)	125	0	3
	160	1	2		250	3	4
Multiple (IVA,K)	32	^d	2	Multiple (IVA,L)	50	^d	2
	64	^d	2		100	0	3
	96	0	2		150	0	3
	128	0	3		200	1	4
	160	1	3		250	2	4
	192	1	3		300	3	5
	224	2	3		350	4	5
Lot Size 150 001 to 500 000				Lot Size 500 001 and over			
Single (IIA,M)	315	3	4	Single (IIA,N)	500	5	6
Double (IIIA,M)	200	1	4	Double (IIIA,N)	315	2	5
	400	4	5		630	6	7
Multiple (IVA,M)	80	^d	3	Multiple (IVA,N)	125	^d	4
	160	0	3		250	1	5
	240	1	4		375	2	6
	320	2	5		500	3	7
	400	3	6		625	5	8
	480	4	6		750	7	9
	560	6	7		875	9	10

^a Do not use samples with pinholes 25 mm from the open end.
^b The table and sample size code letter in ISO 2859 are given in parentheses. The sampling plans are based on an AQL of 0.30 %.
^c The acceptance (AC) and rejection (RE) numbers represent defectives.
^d Acceptance not permitted.

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D. C. 1/10

FILM

SPECIFICATIONS;

4 3/8 Web Width - 2 3/16 Web Width
 Plain White Film
 Material: 195 Cellophane/ 30# White
 Polyethylene (LD)
 Yield: 8040 printed; 8280 plain

Printing: According to item specified by
 Akwell Codes

Method of Printing: Roto Gravure Style reverse
 printing on cellophane with 30# White
 polyethylene extruded to primed side of
 cellophane and slit to 4 3/8 with $\pm 1/64$ "
 tolerance

Pack: unit palletized not to exceed 80 pounds in
 individual shipping carton. Each shipping
 carton to have an individual case contents
 ticket on both outside and inside of the
 carton.

SPECIFICATIONS:

4 3/8 Web Width - 2 3/16" Web Width
 Plain ClearFilm

Material: 195 Cellophane/30# Clear
 Polyethylene

Yield: 8050 MSI printed
 8280 Plain

Printing: According to order specified by
 Akwell Codes

Method of Printing: Roto Gravure Style reverse
 printing on cellophane with 30# Clear
 L.D. Polyethylene extruded to primed
 side of Cellophane and slit to 4 3/8 Web
 with $\pm 1/64$ th tolerance.

Pack: Unit Palletized not to exceed 80# per
 individual shipping carton. Each
 shipping carton to have an individual case
 contents ticket on both inside and outside
 of carton

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W. Lumsden - Secretary
M. Moncrieffs - Marketing Officer
Messrs. Atcheson, Smart, Donaldson Warehouse

Cecil De Cordova, Ltd. (Distributor)

A. Wright - Sales Manager

C. Hoseng - Sales Supervisor

also Mrs. Robertson - Diaglo Packages/Shortwood Pharmacy

Approx. 15 pharmacists in the Kingston area.

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Surindr - Population

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Mr. Kanit - Personnel Officer

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