

## CPSC General Conformity Certification

1. Identification of the product covered by the certificate.  
*Ford Motor Company Consumer Products Labeled (Branded as or Associated with Trade Name):*  
  
*Motorcraft*  
*Power Stroke Diesel*
  
2. Citation to each CPSC product safety regulation to which the product is being certified.  
  
*Ford Motor Company Consumer Products are labeled and packaged in compliance with the following:*  
*Consumer Product Safety Improvement Act of 2008*  
*Federal Hazardous Substances Act*  
*Poison Provision Packaging Act*  
*Federal Regulations 16 CFR 1500 and 16 CFR 1700*
  
3. Identification of the importer or domestic manufacturer as applicable certifying compliance of the product, including the importer or domestic manufacturer's name, full mailing address, and telephone number.  
  
*Ford Motor Company*  
*Henry Ford II World Center*  
*One American Road*  
*Dearborn, MI 48126*
  
4. Contact information for the individual maintaining applicable records and applicable test results.  
  
*Dave M. Lozier*  
*Product Compliance & Service Chemical Supervisor*  
*FCSD--Remanufacturing-Aftermarket Engineering & Service Product Development (SPD)*  
*Phone--313-845-4088*  
*Email--dlozier@ford.com*  
*Location--DCS 2 Rm. 409*
  
5. Date (month and year at a minimum) and place (including city and country or administrative region) where the product was manufactured. (If the same manufacturer operates more than one location in the same city, the street address of the factory in question should be provided.).  
  
*In compliance with California's. REGULATION FOR REDUCING VOLATILE ORGANIC COMPOUND EMISSIONS FROM CONSUMER PRODUCTS SUBCHAPTER 8.5 CONSUMER PRODUCTS Article 2. Consumer Products § 94512. Administrative Requirements (b) Product Dating - all Ford Motor Company Consumer Products are date stamped with the date the product was manufactured.*

All Ford/Motorcraft Chemicals and Lubricants are manufactured and/or packaged by multiple suppliers. Included is date code information from our suppliers. Not every Ford/Motorcraft labeled product will have the same date code or date of manufacture type.

*Date Code Locations:* bottom or lower back panel or side panel.

*Date Code Explanations*

DATE CODE	Explanation				
MM/DD/YY	(MMM=Month i.e. Jan)	(DD=Day of month i.e. 21)	(YY=Year i.e. 05)		
MM/DD/YYYY	(MM=Month i.e. 02)	(DD=Day of month i.e. 21)	(YYYY=Year i.e. 2005)		
MMM/DD/YY	(MMM=Month i.e. Jan)	(DD=Day of month i.e. 21)	(YY=Year i.e. 05)		
YDDD	(Y=Year of Manufacture i.e. 5)	(DDD=Julian date i.e.053)			
YYDDD	(YY=Year of Manufacture i.e. 05)	(DDD=Julian date i.e. 053)			
nA0152An	(015= Julian Date)	(2=Year (2002))	(A=optional letter)	(n=optional number)	
5HK1502A03	(5=last number of year, i.e., 2005)	(H =Letter designating month [ A=Jan, B=Feb, etc.] i.e., H = Aug)	(K=Plant Description)	(1502A=batch code)	(03 = third day of the month)
C670TYFDDD	(C670=supplier code)	(T=Terminal Location)	(Y=year of Mfg)	(F=Fill shift)	(DDD=Julian Date)
4 139 05	(4=Year of Manufacture)	(139=day of year is a Julian date, i.e., 139 = May 19)	(05=shift hour product was packaged)		

*Ford Motor Company Consumer products are packaged for Ford Motor Company by the following suppliers at the following locations:*

*Excelda Manufacturing, Inc. (various locations)  
 Gold Eagle Co. (Chicago, IL)  
 CCI Manufacturing IL Corp. (Lemont, IL)*

- Date and place (including city and country or administrative region) where the product was tested for compliance with the regulation(s) cited above.

*All child resistant packaging used for Ford imported and distributed products are certified as being in compliance with Federal Regulations 16 CFR 1700 and comply with the applicable ASTM standards.D3475-05, Standard Classification of Child-Resistant Packages.*

*Attached to this cover document are the certifications as received from the package suppliers and/or their container sub-suppliers for the Ford Motor Company branded products.*

- Identification of any third-party laboratory on whose testing the certificate depends, including name, full mailing address and telephone number of the laboratory.

*Not applicable as Ford Motor Company FCSD products are not marketed to children.*

## **ATTACHMENTS**

**NEW CONSUMER PRODUCT SAFETY COMMISSION (CPSC) REQUIREMENT  
CERTIFICATE OF CONFORMANCE  
APPLICABLE TO ALL PRODUCTS REGULATED BY THE CPSC**

**11/12/08 ENACTMENT DATE OF THE CONSUMER PRODUCT SAFETY  
IMPROVEMENT ACTION 2008 (CPSIA2008)**

Due to quality issues related to food products and toys manufactured in China, the CPSC has enacted a new requirement titled CPSIA2008.

This modification of the existing CPSC requirements mandates all manufacturers of products regulated by the CPSC to publish a Certificate of Conformity (COC) for all shipments received into and shipped within the USA.

Please see attached email documents that provide details related to this addition to the CPSC enforcement and regulatory requirements.

The following simplified requirement is provided to understand what is required to comply with this new requirement:

1. The manufacture of CPSC regulated products shall certify, using a hardcopy or electronic COC, that all regulated products meet the specific legal requirements defined by the CPSC. (i.e. Federal Hazardous Substance Act (FHSA) or Poison Packaging Act (PPA) as an example).
2. The COC shall document the manufacturer name, applicable CPSC standards, location of manufacturing site, product code interpretation, revision control information, personnel maintaining test documentation documenting closure, label copy, etc. compliance to applicable CPSC regulations.
3. This information can be conveyed using hard copy documents that are placed in each shipping container or may be provided by reference on shipping paper documents referring the receiving location to a URL web site. The web site would contain the COC and allow the receiving location to print out the document.

Attached please find examples of the reference copy that the Gold Eagle Company is printing on our shipping packing lists and the COC that appears on the Gold Eagle Company website containing the COC.

This process can be handled and regulated by the Gold Eagle Company if we generate shipping paper work.

Several of our customers generate their own shipping paper work and need to be aware of this regulatory requirement to formulate a strategy to handle this issue. If you generate shipping papers for products shipped by the Gold Eagle Co, please advise how this regulatory requirement will be handled.

Please review the documents attached regarding this new CPSC regulatory requirement with your regulatory/legal personnel. Contact your Gold Eagle Company sales personnel or Mike Profetto, [mprofetto@goldeagle.com](mailto:mprofetto@goldeagle.com) regarding any clarification required concerning this CPSC regulatory change.

Mike Profetto  
Product Engineering  
(773) 326-6356 Land line

**CONSUMER PRODUCT SAFETY IMPROVEMENT ACT OF 2008 (CPSIA)  
CERTIFICATE of CONFORMANCE**

The Gold Eagle Co. (GEC) is certifying that the following products received by your company meet the Consumer Product Safety Commission (CPSC) standards (were applicable) for:

**Federal Hazardous Substance Act (FHSA)  
Poison Packaging Protection Act (PPPA)**

These products were produced by the GEC located at:

**4400 S. KILDARE AVENUE  
CHICAGO, IL 60632-4372**

The manufacturing code date is located on the individual container and shipping carton, the first 4-5 alpha and numeric characters define the production code date and are interpreted as follows:

**F128 = June 12, 2008**

**A-M:** Month of the year, A=January; B=February; C=March; D= April; E=May; F=June; G=July; H=August; J=September; K=October; L=November and M=December (I is not used)

**Numbers 1-31:** Designates the day of the month

**Last two numbers:** 8=2008; 9=2009; 10=2010; 11=2011, etc.

Please contact Mike Profetto at 773-326-6356 or email questions regarding the CSPIA Certificate of Conformance to [mprofetto@goldeagle.com](mailto:mprofetto@goldeagle.com).

**Issued: 11/12/2008**

**Revised: New**

**Document controlled by: Mike Profetto  
Gold Eagle Company  
4400 S. Kildare Ave.  
Chicago, IL 60632-4372**

**CONSUMER PRODUCT SAFETY IMPROVEMENT ACT OF 2008 (CPSIA)  
CERTIFICATE of CONFORMANCE  
GOLD EAGLE COMPANY**

To review the CPSIA Certificate of Conformance please go to the Gold Eagle Company website located at:

**WWW.GOLDEAGLE.COM**

Please contact Mike Profetto at: [mprofetto@goldeagle.com](mailto:mprofetto@goldeagle.com) or phone 773-326-6356 with questions related to this Certificate of Conformance as mandated by the CSPIA 2008

Issued: 11/12/2008

Updated: New

Controlled by: M. Profetto

# General Conformity Certification

October 2, 2008



This presentation has not been reviewed or approved by the Commission and may not reflect its views

# What Is Certification?

- Certification generally means vouching that a *product complies* with a certain requirement, such as a government standard
- May or may not involve any test laboratory
- May or may not involve a label or mark on the product

# Two Varieties of Product Safety Certification Under CPSC Law

- General Conformity Certification
  - Section 14(a)(1)
  - Akin to a “supplier’s declaration of conformity”
  - This is the focus of this presentation
- Certification of Children’s Products based on Third Part Testing
  - Section 14(a)(2)
  - Many of the same requirements apply
  - This is the focus of the first presentation this afternoon

# What Products Must Be Certified?

- Under prior law, certification was generally required only for *consumer products* subject to *standards* promulgated by the Commission under the *Consumer Product Safety Act*
- The 2008 Act expands the general certification requirement to *all* products *subject to* CPSA bans as well as standards, or to any “*similar rule, ban, standard, or regulation under any other Act* enforced by the Commission.”

# “Subject to”

- Which products are *subject to* a standard or ban is generally spelled out in the regulation
  - Example: Part 1303/Lead Paint Ban
- A product that is *exempt* under a standard is not subject to it, and would not require certification to it
  - Example: crayons not subject to the small parts ban
- A product may be subject to a standard but exempt only from testing: still must be certified

# What Standards, Bans, Rules, Etc., Are “Similar” to Consumer Product Safety Rules?

- FHSA bans and requirements adopted by the Commission, *not bans defined solely by statute (banned hazardous substance by definition)*
- FHSA labeling rules adopted by the Commission
- FFA standards
- PPPA “special packaging” standards
- RSA standard for refrigerators
- Voluntary standards are not covered unless they are made into a mandatory standard, ban, etc.

# Some Future “Similar” Rules

- New lead content limits when phased in
- New standards for durable infant and toddler products when adopted or upgraded by the Commission
- Portions of the ASTM Toy Standard when made mandatory or strengthened by the Commission
- Phthalate bans (permanent and temporary) when effective
- ATV standards when effective (but not the 3-wheel ban)
- Drain covers when required by Pool and Spa Safety Act
- Requirements for portable gasoline containers

# Who Must Certify?

- “*Every* manufacturer” of a product that is subject to a consumer product safety rule or similar rule, ban, standard or regulation *and* which is “*imported* for consumption or warehousing” *or* “*distributed* in commerce”
- The term “manufacturer” includes importers as well as foreign and domestic manufacturers
- Test labs cannot issue section 14 certifications
- If the product bears a private label, the private labeler must also issue a certificate

# Multiple Certifications

- When a product is imported, the foreign manufacturer and the importer *both* must certify unless the Commission, by rule, exempts one or the other of the responsibility
- When a product bears a private label, the manufacturer and the private labeler *both* must certify unless the Commission, by rule, relieves one or the other of the responsibility
- The Commission *has already* pinpointed responsibility for many of the CPSA standards

# Are *All* Imports Covered?

- Certification is required for products that are subject to a standard, ban, etc., and are “imported for consumption or warehousing”
- This *may not* include certain products that are *imported for testing, for trade shows* or for re-export, etc.
- The certification requirement would apply, however, if any of these products is later sold for consumption in the United States

# What Testing Is Required As a Basis for Certification?

- Certification must be based on “a test of each product or upon a reasonable testing program”
- The Commission may *prescribe* a reasonable testing program and may require that testing be done by an *independent third party*
- For children’s products, Congress set a schedule under which *all* certification must eventually be based on third-party testing

# Reasonable Testing Program

- Provide reasonable assurance that the product meets all requirements of the standard
- Type and frequency of tests are up to the issuer of the certificate
  - Not necessary to use the exact test procedure prescribed by the regulations
  - May be advantageous to use stricter test
  - Should be stringent enough to detect variations that would cause a product to fail

# Who Should Test?

- In most CPSA standards, the Commission has said that an importer can certify based on tests conducted by the foreign manufacturer, provided that:
  - A copy of the test records is in English and kept in the US
  - The importer is a resident of the US or has a resident agent
  - Generally, Commission has required test records to be maintained for a period of three years from the date of certification

# Content of Certificates

- Certificates must specify, in English:
  - the manufacturer or private labeler issuing the certificate and any third party on whose testing the certificate depends, by name, address and phone number
  - the date and place where the product was manufactured and date and place of testing
  - contact information for person maintaining test records
  - each applicable standard, ban, etc.
  - May include other info or same info in other languages

# Sample Certificate

1. Identification of the product covered by this certificate:
2. Citation to each CPSC product safety regulation to which this product is being certified:
3. Identification of the foreign manufacturer certifying compliance of the product:
4. Identification of the U.S. importer certifying compliance of the product:
5. Identification of the private labeler certifying compliance of the product (if any):
6. Contact information for the individual maintaining records of test results:
7. Date and place where this product was manufactured:
8. Date and place where this product was tested for compliance with the regulation(s) cited above:
9. Identification of any third-party laboratory on whose testing the certificate depends:

# Availability of Certificates

- Certificates must “*accompany*” each product or shipment of products covered by the same certificate
- A copy of the certificate must be “*furnished* to each distributor or retailer of the product” (no requirement to provide to ultimate consumer)
  - Not necessarily a paper copy
- A copy of the certificate must be made available to the Commission and Customs *upon request*

# Form of Certificates

- The Commission has prescribed the form of the certificate for several CPSA standards
- For example, the certificate must take the form of an *on-product label* under Part 1203 (Bicycle Helmets) and Part 1205 (Walk-Behind Power Lawnmowers)
- Where the form is not prescribed, the certificate could be in the form of a label on the product, an attachment on the shipping container, a separate document, or included in another document such as an invoice, bill, statement, or bill of lading
- Must include all the required information

# *When Is General Conformity Certification Required?*

- The amendments to section 14(a)(1) become effective on November 12, 2008
- Certification will be required for products that are subject to an existing standard, ban, etc., and are manufactured on or after November 12, 2008
- For future standards, bans, etc., certification will generally be required for products which are manufactured on or after the effective date

# Handling of Certificates at the Ports

- There is currently *no requirement to file* a certificate with CBP or any government agency as part of the entry process or otherwise
- Release of the shipment does not depend on presentation of the certificate in every case
- In future, the Commission, after consultation with CBP, may *by rule* provide for *electronic filing* of certificates up to 24 hours before arrival

# Failure to Certify Imports

- Section 17(a)(2) of the Consumer Product Safety Act states that a product offered for importation *“shall be refused admission”* if it is not accompanied by a certificate required under section 14 or if it is accompanied by a false certificate (and the manufacturer has reason to know it is false or misleading in any material respect)

# Refusal of Admission

- Under section 17(e) as amended, products refused admission *must be destroyed* unless the Secretary of Treasury permits export
- All expenses of destruction (including salaries, travel, per diem, etc) shall be paid by the owner or consignee
- If expenses of destruction are not paid, they become a lien against future imports by the same owner or consignee.

# Certification Violations

- CPSA Section 19(a)(6) makes it unlawful for any person either:
  - to *fail to furnish* a certificate required by section 14; or
  - to *issue a false certificate* if the issuer in exercise of due care has reason to know it is false or misleading in any material respect
- Knowing violations of section 19 are subject to civil penalties; knowing and willful violations could lead to imprisonment

# Certification vs. Compliance

- Certification *does not exempt* any product from the requirement to comply with an applicable rule, standard, ban or regulation
- However, under section 19(b), a retailer or distributor who sells or offers for sale a nonconforming product *may have a defense* if it holds a certificate issued in accordance with section 14 (unless it knows that such product does not conform)

# Reporting

- Manufacturers (including importers), distributors and retailers must report to the CPSC *immediately* if they learn that one of their products fails to comply with an applicable consumer product safety rule or “any other rule, regulation, standard, or ban” under the CPSA or any other Act enforced by the Commission
- The expanded reporting requirement is effective 60 days after enactment = October 13, 2008

# Thank You

Gib Mullan, Director, Office of  
Compliance & Field Operations

*Issue Date: 3/24/2009*

***GENERAL CERTIFICATE OF CONFORMITY***

CCI Manufacturing IL Corp. declares that the following products are hereby certified to be compliant with applicable provisions of the Consumer Product Safety Improvement Act of 2008 and related laws as detailed below:

<u>Part Number</u>	<u>Part Description</u>
Motorcraft # 101447 CCI # 20512/36	VC-3 Specialty Orange Engine Coolant with Bittering Agent

Manufactured By:	CCI Manufacturing IL Corp. 15550 Canal Bank Road Lemont, IL 60439
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Blended and packaged by:	Olympic Oil/OWI 5100 W. 70 <sup>th</sup> Place Bedford Park, IL 60638
--------------------------	---

Date of Manufacture:	2/19/2009
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Testing and Compliance Records Retained By:	Dan Aloia CCI Manufacturing IL Corp. 15550 Canal Bank Rd. Lemont, IL 60439 630-685-7538
--	---

This record certifies that the above-referenced product was tested and/or labels affixed to the product were examined and found to be compliant with the following applicable regulations:

FHSA § 1500.14(a)(1) & (b)(1); § 1500.14(b)(1) & (b)(2); 1500.83(a)(15); 1500.121; and 1500.127. PPPA § 1700.14(a)(11)

## Noah Thomas

---

**From:** dleep@oldworldind.com  
**Sent:** Tuesday, March 17, 2009 2:13 PM  
**To:** Noah Thomas  
**Cc:** bmorrisette@oldworldind.com; BHonea@oldworldind.com; rstevens@oldworldind.com  
**Subject:** Certificates of Conformity

Noah:

Bob Morrisette passed on your inquiry of CCI some time ago for my analysis and reply. I apologize for the delay, but I was looking to obtain Consumer Product Safety Commission advice with regard to the issue raised concerning issuance of Certificates of Conformity applicable to our circumstances.

Under the commercial relationship between CCI and Old World, CCI manufactures various antifreeze products that are then sent to an Old World designated blender where the antifreeze is package in bottles bearing labels specified and approved by CCI. In the case of one formulation, Old World adds water to an antifreeze concentrate; in all other cases, Old World simply packages the antifreeze as supplied by CCI.

Under the Consumer Product Safety Commission Act and Consumer Product Safety Improvement Act, CCI is considered the manufacturer of the antifreeze and therefore has the responsibility to issue the Certificate of Conformity (COC) . The CPSC has confirmed CCI should be issuing the Certificates of Conformity for antifreeze it manufactures. This is also the same procedure that Old World follows when Old World has its contract blenders and packagers manufacture Old World antifreeze. Old World prepares COCs for its products, maintains them electronically and makes them available to customers who request them.

Presuming CCI wishes to use the fill date for packaged antifreeze product as date of manufacture, CCI should be able to create its COCs with information routinely provided by Old World. Old World reports to CCI the fill dates for antifreeze packaged by Old World. The bills of lading for any specific shipment of CCI antifreeze also contain the date code reflecting fill date for all antifreeze shipped. The bills of lading link to customer purchase orders.

If Old World can be of any assistance in connection with creation of a general COC form, please let us know. We would be happy to offer the Old World COC form for CCI's consideration.

Finally, since Old World actually procures the caps used for packaging CCI manufactured antifreeze which aspect of packaging is subject to regulation under the Poison Prevention Packaging Act ("PPPA"), please consider this email as certification and assurance by Old World that all caps used in the packaging of CCI antifreeze by Old World is compliant with PPPA regulations 1700.14 (a)(11).

Please feel free to contact me if you wish to discuss any aspect of the above.

Daniel M. Leep  
General Counsel  
Old World Industries, Inc.  
847-559-2230 (phone)  
847-664-7230 (fax)  
[dleep@oldworldind.com](mailto:dleep@oldworldind.com)

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system that may occur while using the data contained in, or transmitted with, this e-mail. If you have received this in error advise us by return e-mail.

**Evaluation of the  
38mm SNL II for  
Senior Use Effectiveness  
for Sunbeam Plastics**

# **PERRITT LABORATORIES**

Since 1973

145 S. Main Street  
Post Office Box 147  
Hightstown, NJ 08520  
(609) 443-4848  
FAX (609) 443-5293

Report to: Sunbeam Plastics  
3245 Kansas Road  
Evansville, IN 47771  
Date: May 6, 1994  
Samples of: 38mm SNL II  
Contract No.: 1110-047  
Submitted by: Mr. Doug Sprick

## OBJECTIVE

The client submitted the above sample to determine if the unit may meet the Senior Use Effectiveness Standards of the Consumer Product Safety Commission for Poison Prevention Packaging.

## PROCEDURE

The test unit was subjected to a two part senior test procedure. Part One was a five minute opening test. Part two was a one minute combined opening and closing test (if appropriate). The field test procedure used is on the following page.

## Panelists

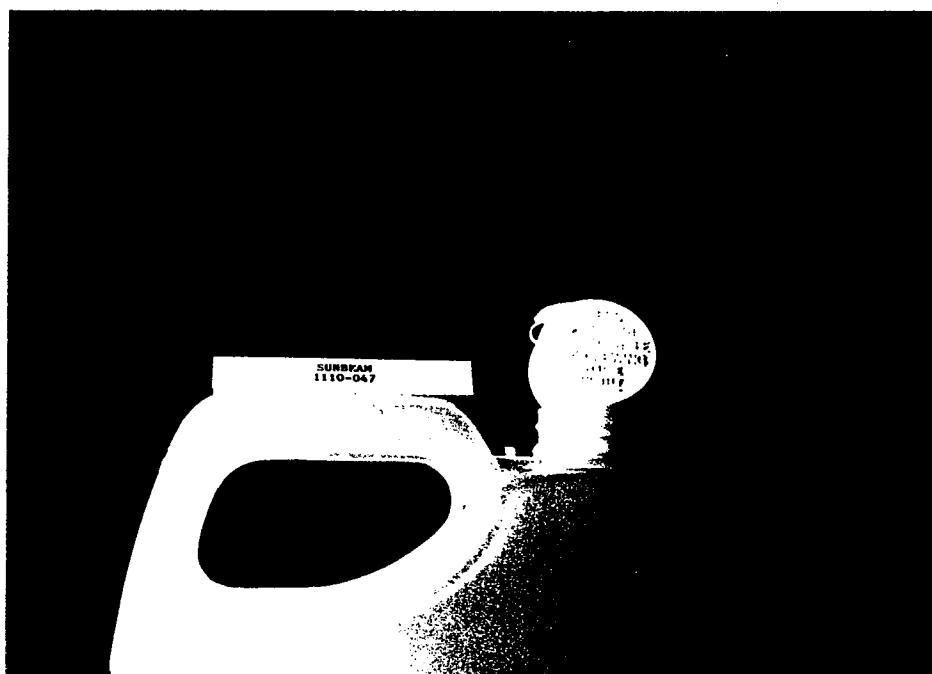
A total of 50 seniors, 60 to 75 years of age, were employed in the study.

## Test Unit

The test unit was the 38mm SNL II. All units tested were empty. Directions to open read: PRESS TAB WITH THUMB WHILE UNSCREWING reclose tightly. A photograph appears in Figure 1 of the report.



Sunbeam Plastics  
Contract No. 1110-047  
May 6, 1994  
Page 3



38mm SNL II

Figure 1

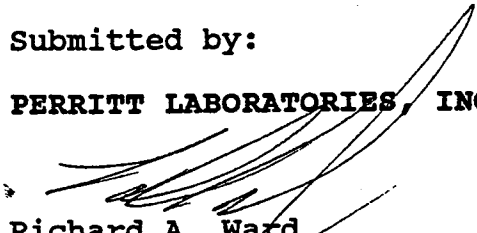
Sunbeam Plastics  
Contract No. 1110-047  
May 6, 1994  
Page 4

RESULTS AND DISCUSSION

Results of the study appear in Table 1 and in the Senior Test Package Data. Table 1 indicates that 48 out of 50 seniors were able to open the unit and 48 seniors properly closed the unit. The Senior Use Effectiveness of this unit is 96.67 percent.

Submitted by:

**PERRITT LABORATORIES, INC.**



Richard A. Ward  
Director of Consumer  
Product Testing

RAW:wp  
Encl.

Evaluation of the 38mm SNL II for Senior Use Effectiveness for Sunbeam Plastics.

Table 1. Container Opening Test Evaluated by Seniors 60 to 75 Years of Age for Senior Use Effectiveness

<u>Panelists Tested</u>		<u>Successful Panelists Without Demonstration</u>		
		<u>1st Open</u>	<u>2nd Open</u>	<u>2nd Close</u>
Female	35	34	34	34
Male	15	15	14	14
Totals	50	49	48	48

Calculated Percent Successful - 96.67

*This is to Certify* I have tested *SUNBEAM PLASTICS CORPORATION'S*

38mm SNAP LOK

*Child resistant closure in accordance to the  
guidelines provided by the  
Consumer Product Safety Commission.*

*I hereby Certify* the results of these tests as follows:

<i>Child-resistant effectiveness</i>	<i>100</i>	<i>% before demonstration</i>
<i>Child-resistant effectiveness</i>	<i>97</i>	<i>% after demonstration</i>
<i>Adult use effectiveness</i>	<i>100</i>	<i>%</i>

*Detailed records of these tests conducted between February 1 and March 26, 1976  
are on file and available for inspection from Sunbeam Plastics Corp. Upon receipt of written request.*

*Gary V. Montgomery*  
\_\_\_\_\_  
Gary V. Montgomery  
\_\_\_\_\_  
Vice President, Engineering  
\_\_\_\_\_  
Sunbeam Plastics Corporation

NOTARY *Linda H. [Signature]*  
My Commission Expires: *June 30, 1977*

ONE GALLON POLYETHYLENE RECTANGULAR CONTAINER  
*Child-Related Research, Inc.*

NUMBER TW-O-B RESEARCH ROAD • UNIVERSITY OF UTAH RESEARCH PARK  
SALT LAKE CITY, UTAH 84112 • 801 582-5165

ROBERT E. BUIE,  
Executive Director

ANTHONY R. TEMPLE, M.D.  
Scientific Director

SAFETY PACKAGING REPORT FORM

STUDY CONDUCTED FOR: Sunbeam Plastic Co.  
7401 Indianapolis Road  
Evansville, Indiana 47711

PACKAGING: 38mm. Sunbeam Snap-lok closure on a one gallon  
polyethylene container.

TYPE OF STUDY: Full Protocol

DATE OF STUDY COMPLETION: March 30, 1976

STUDY FORMAT: Two hundred children, ages 42 to 51 months, evenly  
distributed by age and sex, and 100 adults, were  
tested according to the Consumer Product Safety Com-  
mission's protocol (Federal Register, 38:21247, August  
1973)

EFFECTIVENESS OF PACKAGE:

Children: 97% of the children tested failed to  
open the package during the initial five  
minutes of testing.

90% of the children tested failed to  
open the package during the entire ten  
minutes of testing.

Adults: 100% of the adults tested were able to  
open the package during the five minutes  
of testing.

ANALYSIS OF DATA: A. Number of children to gain entry: 20  
B. Time for children to gain entry:  
1. Number of children to gain entry prior  
to the opening demonstration and instruc-  
tion to use teeth: 6  
2. Number of children to gain entry following  
the opening demonstration and instruction  
to use teeth: 14  
C. Use of teeth:  
1. Number of children who used teeth: 116  
2. Number of children who used teeth and  
did not gain entry in that manner: 106  
3. Number of children who gained entry by using  
teeth: 10  
4. Number of children who gained entry by means  
other than use of teeth: 10

COMMENTS:

The average time for adults to open and resecure the package was 26 seconds. This is a very good closure from the adult acceptability point of view.

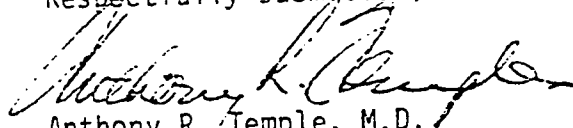
IMPRESSION:

This package, the 38 mm. Sunbeam Snap-lok closure on a one gallon polyethylene container, meets the federal standards for safety required by the Poison Prevention Packaging Act of 1970, a standard promulgated by the Consumer Product Safety Commission as one which will reasonably protect children from entering packaging that would contain potentially harmful substances (Federal Register 38:21247, August 7, 1973)

SUMMARY:

Two hundred children were tested according to the CPSC protocol to see if they could open the 38 mm. Sunbeam Snap-lok closure. The package was 90% effective in that 90% of the children tested failed to open the package during the required ten minutes of testing. One hundred adults were 100% successful in opening and resealing the package within the required five minutes of testing.

Respectfully submitted,



Anthony R. Temple, M.D.  
Scientific Director

ART:dp



**Van Blarcom  
Closures, Inc.**

156 Sanford Street  
Brooklyn, NY 11205  
(718) 855-3810  
Fax 718-935-9855

"Answering your  
needs in closures"

February 12, 2009

Paul Jaworski  
Regulatory Affairs and Product Development Manager  
Andicor Specialty Chemicals

Dear Paul,

The following is the regulatory compliance certification that you requested.

**VBC CHILD RESISTANT CLOSURE COMPLIANCE CERTIFICATE**

VBC's Saf-Cap, Saf Cap I, Saf Cap III and Saf Cap III-A, are classified as type 1A child resistant closures, as stipulated by ASTM in D3475, they are re-closable continuous thread closures, the child resistant mechanism is described as "random push down while turning; no orientation of the push down force is necessary".

I certify that these designs have been tested with standard industry bottles, by independent laboratories, and that it was determined that they are in compliance with CFR title 16, part 1700 with final rule changes cited in the federal register, Vol. 60, No. 140, Friday, July 21,1995, pp.37710 to 37744. VBC child resistant closure designs were tested between 1995 and 2003.

The primary testing laboratory utilized by VBC to test these closure designs is Perritt Laboratories. They are located at 145 South Main Street, P.O. Box 147, Hightstown, NJ 08520.

VBC manufactures Saf-Cap, Saf Cap I, Saf Cap III and Saf Cap III-A closures at our Brooklyn NY manufacturing complex. The manufacturing dates for each order produced are included on our Certificate of Analysis, which is provided to our customers for each batch produced.

If I can be of any additional assistance, please feel free to contact me.

Sincerely yours,

VBC, Inc.

*Anthony Scuderi*

Anthony Scuderi  
Quality Manager

We at Van Blarcom Closures, Inc. can only submit caps and liners to you for testing. In order to insure a proper package, your testing must be performed for both closure/bottle compatibility (including child resistance) and closure liner/product compatibility. You as our customer have the full responsibility of testing the above and also making your customer aware that the testing procedures were performed

**Evaluation of the  
28mm CONTINUOUS THREAD CLOSURE  
ON A 30ml HDPE ROUND BOTTLE as a  
Poison Prevention Package  
with Resecuring Effectiveness  
for Mold-Rite Plastics Inc.**



TESTING  
NO. 1457S111

July 2, 1997

George Gryger  
Mold-Rite Plastics Inc.  
1 Plant Street, PO Box 160  
Plattsburgh, NY 12901

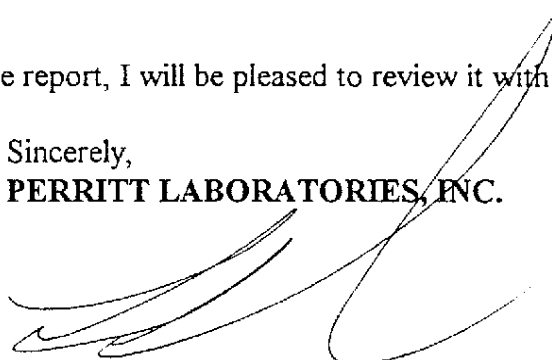
Dear Mr. Gryger,

Herein is our report titled "Evaluation of the 28mm CONTINUOUS THREAD CLOSURE ON A 30ml HDPE ROUND BOTTLE as a Poison Prevention Package with Resecuring Effectiveness for Mold-Rite Plastics Inc."

The test unit was evaluated by using the Consumer Product Safety Commission Protocol and Standards. In the study the test unit fulfills the requirements for Poison Prevention Packaging with resealing effectiveness as per the Code of Federal Regulations (C.F.R.) Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744.

After you have had an opportunity to read the report, I will be pleased to review it with you.

Sincerely,  
**PERRITT LABORATORIES, INC.**



Richard A. Ward  
Director of Consumer Product Testing

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## I. SUMMARY

Report to: Mold-Rite Plastics Inc.  
1 Plant Street, PO Box 160  
Plattsburgh, NY 12901  
Date: July 2, 1997  
Samples of: 28mm CONTINUOUS THREAD CLOSURE ON  
A 30ml HDPE ROUND BOTTLE  
Contract No.: 1206-006  
Samples Received: May 8, 1997  
Submitted by: George Gryger

### Objective

The client submitted the above sample for a study to determine if the unit is in compliance with the Consumer Product Safety Commission (CPSC) protocol and standards for poison prevention packaging with resealing effectiveness as per the Code of Federal Regulations (C.F.R.) Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744.

### Procedures

The protocol for the evaluation of packaging for poison prevention (C.F.R. Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744) was strictly adhered to for this study.

### Panelists

In the course of this study 100 children (42 to 51 months of age) and 100 seniors (50 to 70 year-olds, 70% female) were employed. An additional 100 children were employed to test the packages that the seniors reclosed.

### Results

Results of the study indicate that the 28mm CONTINUOUS THREAD CLOSURE ON A 30ml HDPE ROUND BOTTLE fulfills the standards for poison prevention packaging with resealing effectiveness according to C.F.R. Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744.

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## II. INTRODUCTION

Mold-Rite Plastics Inc. wished to determine if the 28mm CONTINUOUS THREAD CLOSURE ON A 30ml HDPE ROUND BOTTLE fulfills the Consumer Product Safety Commission's (CPSC) standards and protocols for poison prevention packaging with resealing effectiveness set forth in the Code of Federal Regulations Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744. Perritt Laboratories, Inc., a NAMAS accredited laboratory<sup>1</sup> for testing child-resistant packaging according to the CPSC protocol, was requested to evaluate the packaging using the above protocol.

Perritt Laboratories, Inc., an independent testing laboratory, has been evaluating child-resistant packaging for both industry and government for over twenty years. The company is recognized as the leader in the field by virtue of having employed hundreds of thousands of panelists and evaluated thousands of packaging concepts for child-resistance. Perritt Laboratories, Inc. utilizes standard operating procedures (SOP's), along with quality assurance programs in accordance with good laboratory practices (GLP) for non-clinical laboratories.

In the course of this evaluation, the packaging was tested with panels consisting of 100 seniors (50 to 70 year-olds, 70% female) and 100 children (42 to 51 months of age, evenly distributed) obtained from nursery schools, day care centers and civic groups. An additional 100 children were also employed to test the packages that the seniors reclosed. The data derived from the study were assembled in a meaningful fashion and reviewed to determine whether the packaging met the cited standard for poison prevention packaging with resealing effectiveness presented herein.

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1

Perritt Laboratories, Inc. received its updated NAMAS accreditation (#1457 SIII) for testing packaging for child-resistance according to CPSC's final ruling published in the Federal Register, Vol. 60, No. 140, pp. 37710 to 37744 in August of 1995.

NAMAS is the National Measurement Accreditation Service of the United Kingdom. Organizations accredited by NAMAS meet the requirements of EN 45001, ISO Guide 25 and the relevant requirements of the ISO 9000/EN 29000/BS 5750 series of standards, including those of the model described in ISO 9002/EN 29002/BS 5750 Part 2 when acting as suppliers producing test results.

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### III. PROCEDURE

The following standard and protocol was adhered to in this study.

#### Protocol

Code of Federal Regulations Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744:

#### 1700.20 Testing procedure for testing special packaging.

(a) Test protocols - (1) General requirements - (i) Requirements for packaging. As specified in § 1700.15(b), special packaging is required to meet the child test requirements and the applicable adult test requirements of this § 1700.20.

(ii) Condition of packages to be tested. (A) Tamper-resistant feature. Any tamper-resistant feature of the package to be tested shall be removed prior to testing unless it is part of the package's child-resistant design. Where a package is supplied to the consumer in an outer package that is not part of the package's child-resistant design, one of the following situations applies.

(1) In the child test, the package is removed from the outer package, and the outer package is not given to the child.

(2) In both the adult tests, if the outer package bears instructions for how to open or properly resecure the package, the package shall be given to the test subject in the outer package. The time required to remove the package from the outer packages is not counted in the times allowed for attempting to open and, if appropriate, reclose the package.

(3) In both the adult tests, if the outer package does not bear any instructions relevant to the test, the package will be removed from the outer package, and the outer package is not given to the test subject.

(B) Reclosable packages - adult tests. In both the adult tests, reclosable packages, if assembled by the testing agency, shall be properly secured at least 72 hours prior to beginning the test to allow the materials (e.g., the closure liner) to "take a set." If assembled by the testing agency, torque-dependent closures shall be secured at the same on-torque as applied on the packaging line. Application torques must be recorded in the test report. All packages shall be handled so that no damage or jarring will occur during storage or transportation. The packages shall not be exposed to extreme conditions of heat or cold. The packages shall be tested at room temperature.

(2) Child test - (i) Test subjects. (A) Selection criteria. Use from 1 to 4 groups of 50 children, as required under the sequential testing criteria in table 1. No more than 20 percent of the children in each group shall be tested at or obtained from any given site. Each group of children shall be randomly selected as to age, subject to the limitations set

forth below. Thirty percent of the children in each group shall be of age 42-44 months, 40 percent of the children in each group shall be of age 45-48 months, and 30 percent of the children in each group shall be of age 49-51 months. The children's ages shall be calculated as follows:

(1) Arrange the birth date and test date by the numerical designations for month, day, and year.

(2) Subtract the month, day, year numbers for the birth date from the respective numbers for the test date. This may result in negative numbers for the months or days.

(3) Multiply the difference in years by 12 to obtain the number of months in the difference in years, and add this value to the number of months that was obtained when the birth date was subtracted from the test date. This figure either will remain the same or be adjusted up or down by 1 month, depending on the number of days obtained in the subtraction of the birth date from the test date.

(4) If the number of days obtained by subtracting the days in the birth date from the days in the test date is +16 or more, 1 month is added to the number of months obtained above. If the number of days is -16 or less, subtract 1 month. If the number of days is between -15 and +15 inclusive, no change is made in the number of months.

(B) Gender distribution. The difference between the number of boys and the number of girls in each age range shall not exceed 10 percent of the number of children in that range. The children selected should have no obvious or overt physical or mental handicap. Each child's parent or guardian shall read and sign a consent form prior to the child's participation. (The Commission staff will not disregard the results of tests performed by other parties simply because informed consent for children is not obtained.)

(ii) Test failures. A test failure shall be any child who opens the special packaging or gains access to its contents. In the case of unit packaging, however, a test failure shall be any child who opens or gains access to the number of individual units which constitute the amount that may produce serious personal injury or serious illness, or a child who opens or gains access to more than 8 individual units, whichever number is lower, during the full 10 minutes of testing. The number of units a child opens or gains access to is interpreted as the individual units from which the product has been or can be removed in whole or in part. The determination of the amount of substance that may produce serious personal injury or serious illness shall be based on a 25-pound child. Manufacturers or packagers intending to use unit packaging for a substance requiring special packaging are requested to submit such toxicological data to the Commission's Office of Compliance.

(iii) Sequential test. The sequential test is initially conducted using 50 children, and, depending on the results, the criteria in Table 1 determine whether the package is either child-resistant or not child-resistant or whether further testing is required. Further testing is required if the results are inconclusive and involves the use of one or more additional groups of 50 children each, up to a maximum of 200 children. No individual shall administer the test to more than 30 percent of the children tested in each group. Table 1 gives the acceptance (pass), continue testing, and rejection (fail) criteria to be

TABLE 1. - Number of Openings: Acceptance (Pass), Continue Testing, and Rejection (Fail) Criteria for the First 5 minutes and the Full 10 minutes of the Children's Protocol Test

Test Panel	Cumulative number of children	Package openings					
		First 5 minutes			Full 10 minutes		
		Pass	Continue	Fail	Pass	Continue	Fail
1....	50	0-3	4-10	11+	0-5	6-14	15+
2....	100	4-10	11-18	19+	6-15	16-24	25+
3....	150	11-18	19-25	26+	16-25	26-34	35+
4....	200	19-30	.....	31+	26-40	.....	41+

used for the first 5 minutes and the full 10 minutes of the children's test. If the test continues past the initial 50-child panel, the package openings shown in Table 1 are cumulative.

(iv) Test procedures. The children shall be divided into groups of two. The testing shall be done in a location that is familiar to the children; for example, their customary nursery school or regular kindergarten. No child shall test more than two special packages. When more than one special package is being tested, each package shall be of a different ASTM type and they shall be presented to the paired children in random order. This order shall be recorded. The children shall be tested by the procedure incorporated in the following test instructions:

**Standardized Child Test Instructions**

1. Reclosable packages, if assembled by the testing agency, shall be properly secured at least 72 hours prior to the opening described in instruction number 3 to allow the materials, (e.g. the closure liner), to "take a set." Application torques must be recorded in the test report.

2. All packages shall be handled so that no damage or jarring will occur during storage or transportation. The packages shall not be exposed to extreme conditions of heat or cold. The packages shall be tested at room temperature.

3. Reclosable packages shall be opened and properly resecured one time (or more if appropriate), by the testing agency or other adult prior to testing. The opening and resecuring shall not be done in the presence of the children. (In the adult-resecuring test, the tester must not open and resecure the package prior to the test.) If multiple openings/resecurings are to be used, each of four (4) testers shall open and properly resecure one fourth of the packages once and then shall open and properly resecure each package a second, third, fourth, through tenth (or other specified number) time, in the

same sequence as the first opening and resealing. The packages shall not be opened and resealed again prior to testing. The name of each tester and the package numbers that he/she opens and reseals shall be recorded and reported. It is not necessary for the tester to protocol test the packages that they opened and resealed.

4. The child shall have no overt physical or mental handicaps. No child with a permanent or temporary illness, injury, or handicap that would interfere with his/her effective participation shall be included in the test.

5. The testing shall take place in a well-lighted location that is familiar to the children and that is isolated from all distractions.

6. The tester, or another adult, shall escort a pair of children to the test area. The tester shall seat the two children so that there is no visual barrier between the children and the tester.

7. The tester shall talk to the children to make them feel at ease.

8. The children shall not be given the impression that they are in a race or contest. They are not to be told that the test is a game or that it is fun. They are not to be offered a reward.

9. The tester shall record all data prior to, or after, the test so that full attention can be on the children during the test period.

10. The tester shall use a stopwatch(s) or other timing device to time the number of seconds it takes the child to open the package and to time the 5-minute test periods.

11. To begin the test, the tester shall hand the children identical packages and say, "PLEASE TRY TO OPEN THIS FOR ME."

12. If a child refuses to participate after the test has started, the tester shall reassure the child and gently encourage the child to try. If the child continues to refuse, the tester shall ask the child to hold the package in his/her lap until the other child is finished. This pair of children shall not be eliminated from the results unless the refusing child disrupts the participation of the other child.

13. Each child shall be given up to 5 minutes to open his/her package. The tester shall watch the children at all times during the test. The tester shall minimize conversations with the children as long as they continue to attempt to open their packages. The tester shall not discourage the children verbally or with facial expressions. If a child gets frustrated or bored and stops trying to open his/her package, the tester shall reassure the child and gently encourage the child to keep trying (e.g., "please try to open the package").

14. The children shall be allowed freedom of movement to work on their packages as long as the tester can watch both children (e.g., they can stand up, get down on the floor, or bang or pry the package).

15. If a child is endangering himself or others at any time, the test shall be stopped and the pair of children eliminated from the final results.

16. The children shall be allowed to talk to each other about opening the packages and shall be allowed to watch each other try to open the packages.

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17. A child shall not be allowed to try to open the other child's package.

18. If a child opens his/her package, the tester shall say, "THANK YOU," take the package from the child and put it out of the child's reach. The child shall not be asked to open the package a second time.

19. At the end of the 5-minute period, the tester shall demonstrate how to open the package if either child has not opened his or her package. A separate "demo" package shall be used for the demonstration.

20. Prior to beginning the demonstration, the tester shall ask the children to set their packages aside. The children shall not be allowed to continue to try to open their packages during the demonstration period.

21. The tester shall say, "WATCH ME OPEN MY PACKAGE."

22. Once the tester gets the children's full attention, the tester shall hold the demo package approximately two feet from the children and open the package at a normal speed as if the tester were going to use the contents. There shall be no exaggerated opening movements.

23. The tester shall not discuss or describe how to open the package.

24. To begin the second 5-minute period, the tester shall say, "NOW YOU TRY TO OPEN YOUR PACKAGES."

25. If one or both children have not used their teeth to try to open their packages during the first 5 minutes, the tester shall say immediately before beginning the second 5-minute period, "YOU CAN USE YOUR TEETH IF YOU WANT TO." This is the only statement that the tester shall make about using teeth.

26. The test shall continue for an additional 5 minutes or until both children have opened their packages, whichever comes first.

27. At the end of the test period, the tester shall say, "THANK YOU FOR HELPING." If children were told that they could use their teeth, the tester shall say, "I KNOW I TOLD YOU THAT YOU COULD USE YOUR TEETH TODAY, BUT YOU SHOULD NOT PUT THINGS LIKE THIS IN YOUR MOUTH AGAIN." In addition, the tester shall say, "NEVER OPEN PACKAGES LIKE THIS WHEN YOU ARE BY YOURSELF. THIS KIND OF PACKAGE MIGHT HAVE SOMETHING IN IT THAT WOULD MAKE YOU SICK."

28. The children shall be escorted back to their classroom or other supervised area by the tester or another adult.

29. If the children are to participate in a second test, the tester shall have them stand up and stretch for a short time before beginning the second test. The tester shall take care that the children do not disrupt other tests in progress.

(3) Senior-adult panel - (i) Test subjects. Use a group of 100 senior adults. Not more than 24 percent of the senior adults tested shall be obtained from or tested at any one site. Each group of senior adults shall be randomly selected as to age, subject to the limitations set forth below. Twenty-five percent of the participants shall be 50-54 years of age, 25% of participants shall be 55-59 years of age, and 50% of the participants shall be

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60-70 years old. Seventy percent of the participants of ages 50-59 and ages 60-70 shall be female (17 or 18 females shall be apportioned to the 50-54 year age group). No individual tester shall administer the test to more than 35% of the senior adults tested. The adults selected should have no obvious or overt physical or mental disability.

(ii) Screening procedures. Participants who are unable to open the packaging being tested in the first 5-minute time period, are given a screening test. The screening tests for this purpose shall use two packages with conventional (not child-resistant (CR) or "special") closures. One closure shall be a plastic snap closure and the other a CT plastic closure. Each closure shall have a diameter of 28 mm  $\pm$  18%, and the CT closures shall have been resecured 72 hours before testing at 10 inch-pounds of torque. The containers for both the snap- and Ct-type closures shall be round plastic containers, in sizes of 2 ounce  $\pm$  ½ ounce for the CT-type closure and 8 drams  $\pm$  4 drams for the snap-type closure. Persons who cannot open and close both of the screening packages in 1-minute screening tests shall not be counted as participants in the senior-adult panel.

(iii) SAUE. The senior adult use effectiveness (SAUE) is the percentage of adults who both opened the package in the first (5-minute) test period and opened and (if appropriate) properly resecured the package in the 1-minute test period.

(iv) Test procedures. The senior adults shall be tested individually, rather than in groups of two or more. The senior adults shall receive only such printed instructions on how to open and properly secure the special packaging as will appear on or accompany the package as it is delivered to the consumer. The senior-adult panel is tested according to the procedure incorporated in the following senior-adult panel test instructions:

### **Test Instructions for Senior Test**

The following test instructions are used for all senior tests. If non-reclosable packages are being tested, the commands to close the package are eliminated.

1. No adult with a permanent or temporary illness, injury, or disability which would interfere with his/her effective participation shall be included in the test.

2. Each adult shall read and sign a consent form prior to participating. Any appropriate language from the consent form may be used to recruit potential participants. The form shall include the basic elements of informed consent as defined in 16 CFR 1028.116. Before beginning the test, the tester shall say, "PLEASE READ AND SIGN THIS CONSENT FORM." If an adult cannot read the consent form for any reason (forgot glasses, illiterate, etc.), he/she shall not participate in the test.

3. Each adult shall participate individually and not in the presence of other participants or onlookers.

4. The tests shall be conducted in well-lighted and distraction-free areas.

5. Records shall be filled in before or after the test, so that the tester's full attention is on the participant during the test period. Recording the test times to open and resecure the packages are the only exceptions.

6. To begin the first 5-minute test period, the tester says, "I AM GOING TO ASK YOU TO OPEN AND PROPERLY CLOSE THESE TWO IDENTICAL PACKAGES ACCORDING TO THE INSTRUCTIONS FOUND ON THE CAP." (Specify other instruction locations if appropriate.)

7. The first package is handed to the participant by the tester, who says, "PLEASE OPEN THIS PACKAGE ACCORDING THE DIRECTIONS OF THE CAP." (Specify other instruction locations if appropriate.) If the package contains product, the tester shall say, "PLEASE EMPTY THE (PILLS, TABLETS, CONTENTS, ETC.) INTO THIS CONTAINER." After the participant opens the package, the tester says, "PLEASE CLOSE THE PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS OF THE CAP." (Specify other instruction locations if appropriate)

8. Participants are allowed up to 5 minutes to read the instructions and open and close the package. The tester uses a stopwatch(s) or other timing device to time the opening and resealing times. The elapsed times in seconds to open the package and to close the package are recorded on the data sheet as two separate times.

9. After 5 minutes, or when the participant has opened and closed the package, whichever comes first, the tester shall take all test materials from the participant. The participant may remove and replace the closure more than once if the participant initiates these actions. If the participant does not open the package and stops trying to open it before the end of the 5-minute period, the tester shall say, "ARE YOU FINISHED WITH THAT PACKAGE, OR WOULD YOU LIKE TO TRY AGAIN?" If the participant indicates that he/she is finished or cannot open the package and does not wish to continue trying, skip to Instruction 13.

10. To begin the second test period, the tester shall give the participant another, but identical, package and say, "THIS IS AN IDENTICAL PACKAGE. PLEASE OPEN IT ACCORDING TO THE INSTRUCTIONS ON THE CAP." (Specify other instruction locations if appropriate.) If the package contains product, the tester shall say, "PLEASE EMPTY THE (PILLS, TABLETS, CONTENTS, ETC.) INTO THIS CONTAINER." After the participant opens the package, the tester says, "PLEASE CLOSE THIS PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS ON THE CAP." (Specify other instruction locations if appropriate.)

11. The participants are allowed up to 1 minute (60 full seconds) to open and close the package. The elapsed times in seconds to open and to close the package are recorded on the data sheet as two separate times. The time that elapses between the opening of the package and the end of the instruction to close the package is not counted as part of the 1-minute test time.

12. After the 1-minute test, or when the participant has opened and closed the package, whichever comes first, the tester shall take all the test materials from the participant. The participant shall not be allowed to handle the package again. If the participant does not open the package and stops trying to open it before the end of the 1-minute period, the tester shall say, "ARE YOU FINISHED WITH THAT PACKAGE, OR WOULD YOU LIKE TO TRY AGAIN?" If the participant indicates that he/she is finished or cannot open the package and does not wish to continue trying, this shall be counted as a failure of the 1-minute test.

13. Participants who do not open the package in the first 5-minute test period are asked to open and close two non-child-resistant screening packages. The participants are given a 1-minute test period for each package. The tester shall give the participant a package and say, "PLEASE OPEN AND PROPERLY CLOSE THIS PACKAGE." The tester records the time for opening and closing, or 61 seconds, whichever is less, on the data sheet. The tester then gives the participant the second package and says, "PLEASE OPEN AND PROPERLY CLOSE THIS PACKAGE." The times to open and resecure or 61 seconds, whichever is less, shall be recorded on the data sheet.

14. Participants who cannot open and resecure both of the non-child-resistant screening packages are not counted as part of the 100-senior panel. Additional participants are selected and tested.

15. No adult may participate in more than two tests per sitting. If a person participates in two tests, the packages tested shall not be the same ASTM type of package.

16. If more adults in a sex or age group are tested than are necessary to determine SAUE, the last person(s) tested shall be eliminated from that group.

(4) Younger-adult panel. (i) One hundred adults, age 18 to 45 inclusive, with no overt physical or mental handicaps, and 70 percent of whom are female, shall comprise the test panel for younger adults. Not more than 35% of adults shall be obtained or tested at any one site. No individual tester shall administer the test to more than 35% of the adults tested. The adults shall be tested individually, rather than in groups of two or more. The adults shall receive only such printed instructions on how to open and properly resecure the special packaging as will appear on the package as it is delivered to the consumer. Five minutes shall be allowed to complete the opening and, if appropriate, the resealing process.

(ii) Records shall be kept of the number of adults unable to open and of the number of the other adults tested who fail to properly resecure the special packaging. The number adults who successfully open the special packaging and then properly resecure the special packaging (if resealing is appropriate) is the percent of adult-use effectiveness of the special packaging. In the case of unit packaging, the percent of adult-use effectiveness shall be the number of adults who successfully open a single(unit) package.

(iii) Adult-use effectiveness of not less than 90 percent.

#### **Adult-Resecuring Procedure**

1. After the adult participant in either the senior-adult test of 16 CFR 1700.20(a)(3) or the younger-adult test of 16 CFR 1700.20(a)(4) has resealed the package, or at the end of the test period (whichever comes first), the tester shall take the package and place it out of reach. The adult participant shall not be allowed to handle the package again.

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2. The packages that have been opened and appear to be resecured by adults shall be tested by children according the child-test procedures to determine if the packages have been properly resecured. The packages are given to the children without being opened or resecured again for any purpose.

3. Using the results of the adult tests and the tests of apparently-secured package by children, the adult use effectiveness is calculated as follows:

a. Adult use effectiveness.

1. The number of adult opening and resealing failures, plus the number of packages that were opened by the children during the full 10-minute test that exceeds 20% of the apparently-secured packages, equals the total number of failures.

2. The total number of packages tested by adults (which is 100) minus the total number of failures equals the percent adult-use effectiveness.

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### The Package

The test package was the 28mm CONTINUOUS THREAD CLOSURE ON A 30ml HDPE ROUND BOTTLE. For purposes of this test, all of the units tested were empty and received assembled at 10 Inch Pounds of Torque. Directions to open the package read: OPEN: PUSH DOWN & TURN---CLOSE TIGHTLY. A picture of the package appears in Figure 1 of this report.

### Panelists

In the child testing phase of this study, 100 children between the ages of 42 and 51 months distributed into three age groups (42-44, 45-48, and 49-51 months, evenly distributed by sex) were employed.

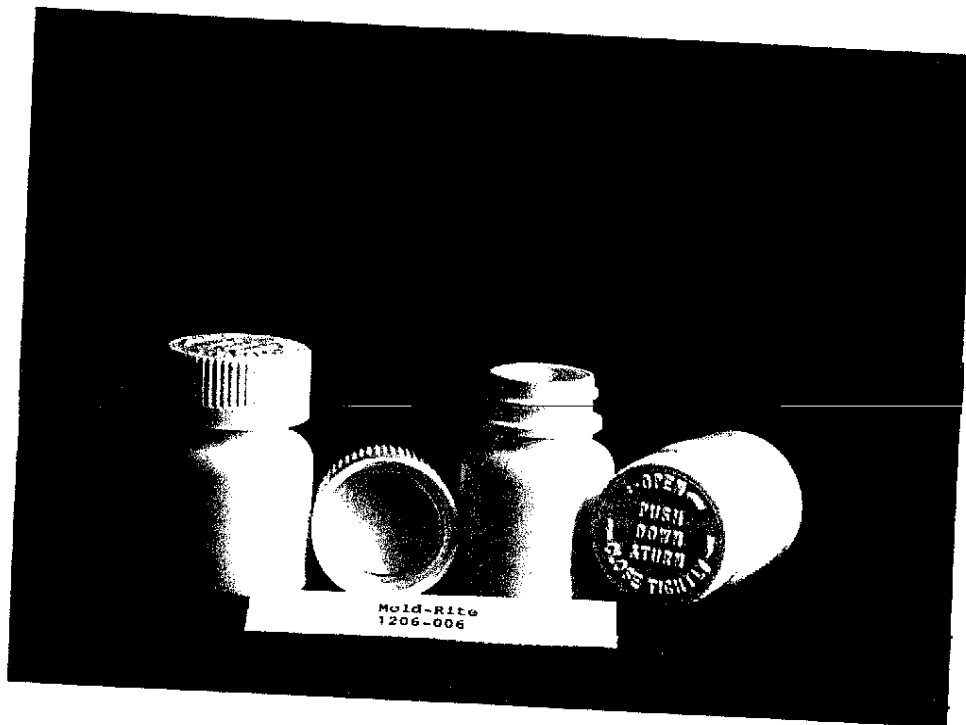
Seniors (100) employed in the study also satisfied the requirements of the protocol, with ages ranging from 50 to 70 years of age divided into three age groups (50-54, 55-59, and 60-70 years old with 70% female).

An additional 100 children were employed to determine if the senior-adult panelists properly closed the packages.

### Test supervisor(s)

Test supervisor(s) were instructed to conduct the evaluation of the packaging in strict accordance with the C.F.R. Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744. To ensure these procedures were adhered to, our complete quality system was followed, including periodic observations throughout the package evaluation.

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28mm CONTINUOUS THREAD CLOSURE  
ON A 30ml HDPE ROUND BOTTLE  
Figure 1

Mold-Rite Plastics Inc.  
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#### IV. RESULTS AND DISCUSSION

Results of this study appear in the tables section of the report. These tables represent a compilation of all data obtained during the study. For clarity in presentation and discussion of this information, the following features will be used as the major points of discussion:

- \* Child-resistant effectiveness
- \* Senior-use effectiveness
- \* Senior-resecuring use effectiveness
- \* Meeting C.F.R. Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744.

##### Child-resistant effectiveness

Results of the package evaluation by the 100 child panelists appear in Table 1 of the report. From this table it will be noted that 7 children were successful in opening the packaging before demonstration and 1 child was successful in opening the packaging following a demonstration for a total of 8 successful child panelists. This represents a child-resistant effectiveness of 92%.

##### Senior-use effectiveness

The senior panel consisted of 70 females and 30 males. Results of the senior test appear in Table 2 of this report. A total of 25 of the 25 seniors in the 50 to 54 year old age group were successful in opening the first package and opening and properly closing the second package, 25 of the 25 seniors in the 55 to 59 year old age group were successful, and 50 of the 50 seniors were successful in the 60 to 70 year old age group. The SAUE was calculated at 100 minus 0 for a final SAUE, including the resealing test, of 100 for the 100 seniors and 100 children who tested the packages apparently resealed by the seniors. The exact opening and closing times are given in the Senior Test Packaging Data.

##### Senior-resecuring use effectiveness

A group of 100 children were employed to test the packages that were apparently resealed by the senior-adults. Results of the senior-resecuring test with children appear in Table 3 of this report. A total of 17 children were successful in opening the apparently resealed packages. The amount over 20% ( $100 \times .2 = 20$ ) is 0, and is subtracted from the calculated senior-use effectiveness.

Meeting C.F.R. Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744.

The 28mm CONTINUOUS THREAD CLOSURE ON A 30ml HDPE ROUND BOTTLE fulfills the standards for poison prevention packaging with resealing effectiveness according to C.F.R. Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744.

Mold-Rite Plastics Inc.  
1206-006  
July 2, 1997

## V. CONCLUSION

The data presented in the report demonstrates that the 28mm CONTINUOUS THREAD CLOSURE ON A 30ml HDPE ROUND BOTTLE fulfills the requirements for poison prevention packaging with resealing effectiveness according to the Code of Federal Regulations Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744.

Mold-Rite Plastics Inc.  
 1206-006  
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Evaluation of the 28mm CONTINUOUS THREAD CLOSURE ON A 30ml HDPE ROUND BOTTLE as a child-resistant package for Mold-Rite Plastics Inc..

Table 1. Package opening test evaluated by children 42 to 51 months of age for child-resistant effectiveness.

<u>Age in Months</u>	<u>Successful Panelists</u>							
	<u>M</u>	<u>F</u>	<u>Total</u>	<u>Before Demo.</u>		<u>After Demo.</u>		<u>Total</u>
				<u>M</u>	<u>F</u>	<u>M</u>	<u>F</u>	
42-44	15	15	30	0	1	0	0	1
45-48	20	20	40	2	1	0	0	3
49-51	15	15	30	0	3	1	0	4
<b>Totals</b>	<b>50</b>	<b>50</b>	<b>100</b>	<b>2</b>	<b>5</b>	<b>1</b>	<b>0</b>	<b>8</b>

**CHILD-RESISTANT EFFECTIVENESS = 92%**

## CHILD TEST - PACKAGE DATA

CLIENT NAME: Mold-Rite Plastics Inc.  
 DESCRIPTION: 28mm C.T./30ml HDPE  
 CONTRACT NO. 1206-006

July 2, 1997

PACKAGE NUMBER	TEST DATE	SITE CODE	INTER- VIEWER	BIRTH DATE	AGE MON.	SEX	OPENING SECONDS 601=NOT OPENED	METHOD
1	5/12/97	C853	12	3/29/93	49	F	601	0
2	5/12/97	C853	12	4/11/93	49	M	601	0
3	5/12/97	C503	14	11/16/93	42	M	601	0
4	5/12/97	C503	14	10/15/93	43	M	601	0
5	5/12/97	C503	14	3/31/93	49	M	601	0
6	5/12/97	C503	14	4/02/93	49	F	601	0
7	5/12/97	C853	12	1/28/93	51	M	601	0
8	5/12/97	C853	12	10/31/93	42	M	601	0
9	5/12/97	C853	12	1/28/93	51	F	601	0
10	5/12/97	C853	12	11/16/93	42	M	601	0
11	5/12/97	C503	14	9/08/93	44	F	601	0
12	5/12/97	C503	14	8/06/93	45	F	601	0
13	5/13/97	C853	17	7/17/93	46	F	601	0
14	5/13/97	C853	17	7/21/93	46	F	601	0
15	5/13/97	C853	17	9/12/93	44	M	601	0
16	5/13/97	C853	17	1/29/93	51	F	601	0
17	5/13/97	C503	16	8/12/93	45	M	601	0
18	5/13/97	C503	16	6/08/93	47	F	601	0
19	5/13/97	C503	16	3/03/93	50	M	601	0
20	5/13/97	C503	16	3/18/93	50	M	601	0
21	5/14/97	C800	12	10/12/93	43	M	601	0
22	5/14/97	C800	12	5/13/93	48	M	601	0
23	5/14/97	C800	14	2/03/93	51	M	601	0
24	5/14/97	C800	14	2/22/93	51	M	601	0
25	5/14/97	C773	14	6/22/93	47	M	601	0
26	5/14/97	C773	14	7/02/93	46	F	601	0
27	5/14/97	C773	12	4/19/93	49	M	328	3
28	5/14/97	C773	12	1/31/93	51	F	245	3
29	5/14/97	C773	12	6/05/93	47	M	601	0
30	5/14/97	C773	12	5/28/93	48	F	26	3
31	5/14/97	C773	14	10/17/93	43	F	601	0
32	5/14/97	C773	14	9/17/93	44	F	601	0
33	5/14/97	C773	12	8/20/93	45	F	601	0
34	5/14/97	C773	12	6/09/93	47	F	601	0
35	5/14/97	C800	12	3/05/93	50	F	125	3
36	5/14/97	C800	12	3/29/93	50	F	601	0
37	5/14/97	C800	14	5/11/93	48	M	601	0
38	5/14/97	C800	14	6/09/93	47	M	601	0
39	5/15/97	C761	17	6/27/93	47	M	601	0
40	5/15/97	C761	17	11/02/93	42	F	601	0
41	5/15/97	C761	17	10/01/93	43	F	110	1
42	5/15/97	C761	17	11/04/93	42	M	601	0
43	5/16/97	C694	16	7/08/93	46	F	601	0
44	5/16/97	C694	16	8/18/93	45	F	601	0
45	5/16/97	C694	16	9/12/93	44	F	601	0
46	5/16/97	C694	16	5/21/93	48	M	601	0
47	5/16/97	C694	16	11/08/93	42	F	601	0
48	5/16/97	C694	16	11/08/93	42	F	601	0
49	5/20/97	C692	16	5/21/93	48	M	601	0
50	5/20/97	C692	16	5/31/93	48	M	601	0

## CHILD TEST - PACKAGE DATA

CLIENT NAME: Mold-Rite Plastics Inc.  
 DESCRIPTION: 28mm C.T./30ml HDPE  
 CONTRACT NO. 1206-006

July 2, 1997

PACKAGE NUMBER	TEST DATE	SITE CODE	INTER- VIEWER	BIRTH DATE	AGE MON.	SEX	OPENING SECONDS	
							601=NOT OPENED	METHOD
51	6/12/97	C514	12	3/03/93	51	M	601	0
52	6/12/97	C514	12	3/30/93	50	M	601	0
53	6/12/97	C514	14	7/27/93	47	M	601	0
54	6/12/97	C514	14	9/09/93	45	F	601	0
55	6/12/97	C514	14	6/23/93	48	M	87	3
56	6/12/97	C514	14	4/29/93	49	F	601	0
57	6/12/97	C514	12	7/19/93	47	F	601	0
58	6/12/97	C514	12	5/27/93	49	M	601	0
59	6/12/97	C514	12	2/28/93	51	F	601	0
60	6/12/97	C514	12	7/15/93	47	M	183	6
61	6/16/97	C061	12	11/20/93	43	M	601	0
62	6/16/97	C061	12	3/26/93	51	F	601	0
63	6/17/97	C064	14	7/20/93	47	F	601	0
64	6/17/97	C064	14	7/14/93	47	F	601	0
65	6/17/97	C525	12	9/03/93	45	F	601	0
66	6/17/97	C525	12	7/30/93	47	M	601	0
67	6/17/97	C525	12	3/08/93	51	M	601	0
68	6/17/97	C525	12	3/23/93	51	F	601	0
69	6/17/97	C064	14	4/08/93	50	F	601	0
70	6/17/97	C064	14	5/03/93	49	F	98	3
71	6/16/97	C629	16	6/17/93	48	M	601	0
72	6/16/97	C629	16	7/13/93	47	M	601	0
73	6/16/97	C629	16	5/20/93	49	M	601	0
74	6/16/97	C629	16	6/12/93	48	M	601	0
75	6/16/97	C629	16	9/17/93	45	M	601	0
76	6/16/97	C629	16	8/13/93	46	F	601	0
77	6/16/97	C629	16	6/14/93	48	M	601	0
78	6/16/97	C629	16	7/04/93	47	F	601	0
79	6/16/97	C629	16	11/18/93	43	M	601	0
80	6/16/97	C629	16	10/01/93	44	F	601	0
81	6/17/97	C064	14	9/07/93	45	M	601	0
82	6/17/97	C064	14	10/04/93	44	F	601	0
83	6/17/97	C525	12	9/21/93	45	F	601	0
84	6/17/97	C525	12	10/02/93	44	M	601	0
85	6/17/97	C064	14	10/16/93	44	M	601	0
86	6/17/97	C064	14	11/19/93	43	M	601	0
87	6/17/97	C525	12	11/22/93	43	M	601	0
88	6/17/97	C525	12	10/18/93	44	F	601	0
89	6/17/97	C064	14	12/16/93	42	M	601	0
90	6/17/97	C064	14	5/20/93	49	F	601	0
91	6/17/97	C525	12	12/06/93	42	F	601	0
92	6/17/97	C525	12	11/26/93	43	M	601	0
93	6/18/97	C841	16	7/03/93	47	F	601	0
94	6/18/97	C841	16	5/02/93	50	F	601	0
95	6/20/97	C546	14	5/04/93	50	M	601	0
96	6/20/97	C546	14	10/11/93	44	F	601	0
97	6/23/97	C538	16	8/15/93	46	F	601	0
98	6/23/97	C538	16	11/05/93	44	F	601	0
99	6/23/97	C538	16	11/23/93	43	F	601	0
100	6/23/97	C538	16	3/15/93	51	M	601	0

Evaluation of the 28mm CONTINUOUS THREAD CLOSURE ON A 30ml  
 HDPE ROUND BOTTLE for senior-use effectiveness for Mold-Rite Plastics Inc..

Table 2. Package opening test evaluated by adults 50 to  
 70 years of age for senior-use effectiveness.

	<u>Panelists Tested</u>	<u>Successful Panelists</u>	
		<u>First Opening</u>	<u>Second Opening and Second Closing</u>
<u>50 - 54 years old:</u>			
Female	18	18	18
Male	7	7	7
<b>Subtotal</b>	<b>25</b>	<b>25</b>	<b>25</b>
<u>55 - 59 years old:</u>			
Female	17	17	17
Male	8	8	8
<b>Subtotal</b>	<b>25</b>	<b>25</b>	<b>25</b>
<u>60 - 70 years old:</u>			
Female	35	35	35
Male	15	15	15
<b>Subtotal</b>	<b>50</b>	<b>50</b>	<b>50</b>

SENIOR-USE EFFECTIVENESS (SAUE) = 100 - 0 = 100%

SENIOR TEST PACKAGE DATA

CLIENT NAME: Mold-Rite Plastics Inc.  
 DESCRIPTION: 28mm C.T./30ml HDPE  
 CONTRACT NO. 1206-006

July 2, 1997

PACKAGE NUMBER	TEST DATE	SITE CODE	INTER-VIEWER	SEX	AGE	FIRST OPENING FAIL = 301 SEC	FIRST CLOSING STOP = 301 SEC	SECOND OPENING FAIL = 61 SEC	SECOND CLOSING FAIL = 61 SEC
1	5/12/97	C994	16	F	59	3	2	3	2
2	5/12/97	C994	16	F	68	6	2	4	2
3	5/12/97	C994	16	F	54	4	2	3	2
4	5/12/97	C994	16	M	52	4	2	4	3
5	5/12/97	C994	16	M	60	8	3	4	3
6	5/12/97	C994	16	M	60	10	3	8	3
7	5/12/97	C994	16	F	52	6	2	4	2
8	5/12/97	C994	16	F	66	7	3	4	2
9	5/12/97	C994	16	M	59	4	2	5	2
10	5/12/97	C994	16	F	53	4	2	4	2
11	5/12/97	C994	16	M	65	7	3	4	3
12	5/12/97	C994	16	F	60	5	3	4	2
13	5/12/97	C994	16	M	61	7	3	4	2
14	5/12/97	C994	16	F	61	4	2	5	2
15	5/12/97	C994	16	M	53	7	2	4	2
16	5/12/97	C994	16	F	50	6	2	3	2
17	5/12/97	C994	16	M	54	4	1	2	1
18	5/12/97	C994	16	M	55	7	2	6	2
19	5/12/97	C994	16	F	59	4	3	4	2
20	5/12/97	C994	16	F	66	7	3	6	3
21	5/12/97	C994	16	F	67	8	3	6	3
22	5/12/97	C994	16	F	60	4	2	4	2
23	5/12/97	C994	16	M	63	3	2	3	2
24	5/12/97	C994	16	M	56	6	3	5	3
25	5/14/97	C967	17	M	53	5	2	4	2
26	5/14/97	C967	17	F	50	6	2	3	2
27	5/14/97	C967	17	F	56	4	2	4	2
28	5/14/97	C967	17	F	67	9	3	6	2
29	5/14/97	C967	17	M	67	5	2	5	2
30	5/14/97	C967	17	F	53	4	2	3	2
31	5/14/97	C967	17	F	65	3	2	3	2
32	5/14/97	C967	17	F	63	7	2	4	2
33	5/14/97	C967	17	F	63	8	3	4	3
34	5/14/97	C967	17	F	62	4	2	4	2
35	5/14/97	C967	17	F	61	5	3	4	2
36	5/14/97	C967	17	M	56	4	2	4	1
37	5/14/97	C967	17	F	62	8	3	6	3
38	5/14/97	C967	17	F	59	4	2	4	2
39	5/14/97	C967	17	M	57	8	2	4	2
40	5/14/97	C967	17	F	61	7	3	5	2
41	5/14/97	C967	17	F	50	5	2	4	2
42	5/14/97	C967	17	M	52	6	3	5	2
43	5/14/97	C967	17	F	53	8	4	6	2
44	5/14/97	C967	17	M	68	7	3	4	2
45	5/14/97	C967	17	F	56	6	3	4	2
46	5/14/97	C967	17	F	63	4	2	4	2
47	5/14/97	C967	17	F	55	3	2	3	2
48	5/14/97	C967	17	F	56	5	3	4	3
49	5/16/97	C947	12	F	69	2	0	3	4
50	5/16/97	C947	14	M	69	3	1	4	3
51	5/16/97	C947	14	M	63	7	3	2	1

SENIOR TEST PACKAGE DATA

CLIENT NAME: Mold-Rite Plastics Inc.  
 DESCRIPTION: 28mm C.T./30ml HDPE  
 CONTRACT NO. 1206-006

July 2, 1997

PACKAGE NUMBER	TEST DATE	SITE CODE	INTER-VIEWER	SEX	AGE	FIRST OPENING FAIL = 301 SEC	FIRST CLOSING STOP = 301 SEC	SECOND OPENING FAIL = 61 SEC	SECOND CLOSING FAIL = 61 SEC
52	5/16/97	C947	12	F	69	16	6	3	2
53	5/16/97	C947	14	F	65	8	2	4	4
54	5/16/97	C947	12	M	70	2	2	1	2
55	5/16/97	C947	14	F	69	7	2	5	3
56	5/16/97	C947	12	F	68	9	5	4	4
57	5/16/97	C947	14	M	66	19	3	5	4
58	5/16/97	C947	12	F	70	5	3	3	3
59	5/16/97	C947	14	M	66	5	3	2	2
60	5/16/97	C947	12	F	64	5	3	3	3
61	5/16/97	C947	14	M	62	2	2	1	14
62	5/16/97	C947	12	F	68	6	3	15	5
63	5/19/97	C997	14	M	52	4	2	2	1
64	5/19/97	C997	14	M	58	4	1	2	1
65	5/19/97	C997	14	F	50	1	1	1	1
66	5/19/97	C997	14	F	56	1	2	1	1
67	5/19/97	C997	14	M	66	2	2	1	14
68	5/19/97	C997	14	M	66	6	3	9	2
69	5/19/97	C997	14	M	54	8	1	3	1
70	5/19/97	C997	14	F	53	11	4	4	2
71	5/19/97	C997	14	F	51	5	4	1	13
72	5/19/97	C997	14	M	57	5	1	2	1
73	5/19/97	C997	14	F	56	3	1	3	1
74	5/28/97	C995	1	F	69	6	2	4	2
75	5/28/97	C995	1	F	66	4	2	4	2
76	5/28/97	C995	1	F	69	8	3	4	3
77	5/28/97	C995	1	F	70	6	3	5	3
78	5/28/97	C995	1	F	51	9	2	6	2
79	5/28/97	C995	1	F	68	7	2	4	2
80	5/28/97	C995	1	F	66	4	2	4	2
81	5/28/97	C995	1	F	52	6	3	4	3
82	5/28/97	C995	1	F	52	5	3	5	2
83	5/28/97	C995	1	F	57	4	3	4	2
84	5/28/97	C995	1	F	70	10	2	6	2
85	5/28/97	C995	1	F	69	4	2	4	2
86	5/28/97	C995	1	F	57	8	3	7	3
87	5/28/97	C995	1	F	63	4	2	3	2
88	5/28/97	C995	1	F	61	6	3	5	3
89	5/28/97	C995	1	F	66	8	4	7	2
90	5/28/97	C995	1	F	55	6	2	4	2
91	5/28/97	C995	1	F	56	3	2	3	2
92	5/28/97	C995	1	F	53	6	2	4	2
93	5/28/97	C995	1	F	51	4	2	4	2
94	5/28/97	C995	16	F	50	4	2	4	2
95	5/28/97	C995	16	F	50	3	2	4	2
96	5/28/97	C995	16	M	55	6	2	4	2
97	5/28/97	C995	16	F	55	7	2	6	2
98	6/02/97	C975	16	F	55	6	2	4	2
99	6/02/97	C975	16	F	55	4	2	4	2
100	6/02/97	C975	16	F	56	6	3	4	2

Mold-Rite Plastics Inc.  
 1206-006  
 July 2, 1997

Evaluation of the 28mm CONTINUOUS THREAD CLOSURE ON A 30ml HDPE ROUND BOTTLE as a child-resistant package for Mold-Rite Plastics Inc..

Table 3. Senior-resecured package opening test evaluated by children 42 to 51 months of age for senior-resecuring effectiveness.

Age in Months	<u>Successful Panelists</u>							
	<u>M</u>	<u>F</u>	<u>Total</u>	<u>Before Demo.</u>		<u>After Demo.</u>		<u>Total</u>
				<u>M</u>	<u>F</u>	<u>M</u>	<u>F</u>	
42-43	15	15	30	1	4	0	0	5
45-48	20	20	40	5	1	1	0	7
49-51	15	15	30	3	2	0	0	5
<b>Totals</b>	<b>50</b>	<b>50</b>	<b>100</b>	<b>9</b>	<b>7</b>	<b>1</b>	<b>0</b>	<b>17</b>

The amount over 20% ( $100 \times .2 = 20$ ) is 0, and is subtracted from the calculated senior-use effectiveness.

## CHILD TEST - PACKAGE DATA

CLIENT NAME: Mold-Rite Plastics Inc.  
 DESCRIPTION: Senior-resecured  
 CONTRACT NO. 1206-006

July 2, 1997

PACKAGE NUMBER	TEST DATE	SITE CODE	INTER- VIEWER	BIRTH DATE	AGE MON.	SEX	OPENING	METHOD
							SECONDS 601=NOT OPENED	
1	5/13/97	C853	17	7/16/93	46	M	601	0
2	5/13/97	C853	17	9/24/93	44	F	601	0
3	5/13/97	C853	17	5/08/93	48	M	601	0
4	5/13/97	C853	17	5/14/93	48	F	601	0
5	5/13/97	C853	17	7/10/93	46	F	601	0
6	5/13/97	C853	17	4/22/93	49	M	601	0
7	5/13/97	C853	17	10/10/93	43	F	210	1
8	5/13/97	C853	17	7/16/93	46	F	601	0
9	5/13/97	C853	17	2/09/93	51	M	601	0
10	5/13/97	C853	17	10/11/93	43	M	601	0
11	5/13/97	C503	16	3/22/93	50	M	601	0
12	5/13/97	C503	16	3/19/93	50	M	116	1
13	5/13/97	C503	16	1/29/93	51	F	601	0
14	5/13/97	C503	16	1/29/93	51	M	601	0
15	5/13/97	C503	16	7/15/93	46	M	601	0
16	5/13/97	C503	16	8/26/93	45	F	601	0
17	5/13/97	C503	16	2/04/93	51	F	201	1
18	5/13/97	C503	16	8/01/93	45	M	601	0
19	5/13/97	C503	16	7/03/93	46	F	601	0
20	5/13/97	C503	16	7/21/93	46	F	601	0
21	5/15/97	C761	16	4/29/93	49	F	601	0
22	5/15/97	C761	16	8/20/93	45	M	130	1
23	5/15/97	C761	16	5/07/93	48	M	601	0
24	5/15/97	C761	16	2/09/93	51	M	601	0
25	5/15/97	C761	16	3/19/93	50	M	601	0
26	5/15/97	C761	16	3/08/93	50	M	601	0
27	5/15/97	C761	16	8/17/93	45	F	601	0
28	5/15/97	C761	16	7/19/93	46	M	601	0
29	5/15/97	C761	16	10/15/93	43	M	601	0
30	5/15/97	C761	16	11/01/93	42	M	601	0
31	5/20/97	C692	17	7/29/93	46	F	601	0
32	5/20/97	C692	17	7/29/93	46	F	601	0
33	5/20/97	C692	17	9/20/93	44	M	601	0
34	5/20/97	C692	17	10/24/93	43	F	601	0
35	5/20/97	C692	17	10/08/93	43	M	601	0
36	5/20/97	C692	17	7/24/93	46	M	119	1
37	5/20/97	C692	17	4/10/93	49	F	601	0
38	5/20/97	C692	17	10/04/93	44	M	601	0
39	5/20/97	C692	17	11/01/93	43	F	601	0
40	5/20/97	C692	17	8/11/93	45	F	601	0
41	5/20/97	C692	16	5/28/93	48	M	601	0
42	5/20/97	C692	16	8/14/93	45	F	601	0
43	5/20/97	C692	16	8/06/93	45	M	601	0
44	5/20/97	C692	16	4/20/93	49	F	601	0
45	5/20/97	C692	16	3/24/93	50	M	601	0
46	5/20/97	C692	16	2/05/93	51	M	601	0
47	5/20/97	C692	16	5/17/93	48	F	601	0
48	5/20/97	C692	16	3/14/93	50	F	601	0
49	5/20/97	C692	16	8/10/93	45	F	601	0
50	5/20/97	C692	16	4/08/93	49	M	601	0

## CHILD TEST - PACKAGE DATA

CLIENT NAME: Mold-Rite Plastics Inc.  
 DESCRIPTION: Senior-resecured  
 CONTRACT NO. 1206-006

July 2, 1997

PACKAGE NUMBER	TEST DATE	SITE CODE	INTER- VIEWER	BIRTH DATE	AGE MON.	SEX	OPENING SECONDS 601=NOT OPENED	METHOD
51	5/21/97	C852	14	8/08/93	45	M	601	0
52	5/21/97	C852	14	10/19/93	43	F	601	0
53	5/21/97	C852	14	11/05/93	43	M	271	3
54	5/21/97	C852	14	10/22/93	43	F	227	3
55	5/23/97	C822	14	7/07/93	47	M	601	0
56	5/23/97	C822	14	10/09/93	43	M	601	0
57	5/23/97	C822	14	9/19/93	44	F	601	0
58	5/23/97	C822	14	6/01/93	48	M	99	3
59	5/23/97	C822	14	2/15/93	51	M	25	3
60	5/23/97	C822	14	10/27/93	43	F	601	0
61	5/23/97	C822	14	6/03/93	48	F	601	0
62	5/23/97	C822	14	11/10/93	42	F	33	3
63	5/23/97	C822	14	12/07/93	42	F	24	3
64	5/23/97	C822	14	8/25/93	45	M	54	3
65	5/28/97	C790	14	2/27/93	51	F	27	3
66	5/28/97	C790	14	5/17/93	48	M	12	3
67	5/28/97	C791	14	3/27/93	50	M	601	0
68	5/28/97	C791	14	3/23/93	50	M	37	3
69	5/28/97	C791	14	8/18/93	45	F	601	0
70	5/28/97	C791	14	4/12/93	50	F	601	0
71	5/28/97	C791	14	7/28/93	46	F	23	3
72	5/28/97	C791	14	2/27/93	51	F	601	0
73	5/30/97	C682	17	10/08/93	44	M	601	0
74	5/30/97	C682	17	11/09/93	43	M	601	0
75	5/30/97	C682	17	3/08/93	51	M	601	0
76	5/30/97	C682	17	6/08/93	48	F	601	0
77	5/30/97	C682	17	7/08/93	47	F	601	0
78	5/30/97	C682	17	4/04/93	50	F	601	0
79	5/30/97	C682	17	7/05/93	47	M	601	0
80	5/30/97	C682	17	3/25/93	50	F	601	0
81	5/30/97	C682	17	9/02/93	45	F	601	0
82	5/30/97	C682	17	11/09/93	43	M	601	0
83	5/30/97	C682	12	11/25/93	42	F	601	0
84	5/30/97	C682	12	2/25/93	51	F	601	0
85	5/30/97	C682	12	3/22/93	50	F	601	0
86	5/30/97	C682	12	10/11/93	44	F	601	0
87	5/30/97	C682	12	6/14/93	48	M	601	0
88	5/30/97	C682	12	10/22/93	43	M	601	0
89	5/30/97	C682	12	9/16/93	44	F	601	0
90	5/30/97	C682	12	4/08/93	50	F	601	0
91	6/02/97	C848	14	5/24/93	48	M	322	6
92	6/02/97	C848	14	6/25/93	47	M	601	0
93	6/02/97	C848	14	12/13/93	42	F	601	0
94	6/02/97	C848	14	9/19/93	44	F	601	0
95	6/03/97	C060	14	8/29/93	45	F	601	0
96	6/03/97	C060	14	8/23/93	45	M	601	0
97	6/03/97	C060	14	12/03/93	42	M	601	0
98	6/03/97	C060	14	3/12/93	51	F	601	0
99	6/03/97	C060	14	12/03/93	42	M	601	0
100	6/03/97	C060	14	12/09/93	42	M	601	0

Mold-Rite Plastics Inc.  
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Test Supervisors

1	-	Shirley Kasper
2	-	Betty Rousseau
3	-	Susan Jakober
4	-	Linda Contiliano
5	-	Lissa Perritt
6	-	Scott Perritt
7	-	Richard Ward
8	-	Kelley Dippold
9	-	Anita Burgey
10	-	Elaine Villani
12	-	Paula Giannotti
14	-	Susan Davies
15	-	Marie Gerland
16	-	Helen Lambert
17	-	Joyce Osborne
19	-	Norma Swale
26	-	Carol Biddenger
27	-	Jody Kloch
28	-	Susan Pazornick

Methods of opening

0	-	Not opened
1	-	Correct method
2	-	Used fingernail
3	-	Used fingers
4	-	Used teeth
5	-	Used feet
6	-	Shelled
7	-	Damaged package
8	-	Touched indicator
9	-	Used teeth and fingers
10	-	Banged on floor
11	-	Caused noticeable leakage

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**Addendum**

**Evaluation of the  
28mm CONTINUOUS THREAD CLOSURE  
ON A 30ml HDPE ROUND BOTTLE as a  
Poison Prevention Package  
with Resecuring Effectiveness  
for Mold-Rite Plastics Inc.**



TESTING  
NO. 1457S111

July 2, 1997

George Gryger  
Mold-Rite Plastics Inc.  
1 Plant Street, PO Box 160  
Plattsburgh, NY 12901

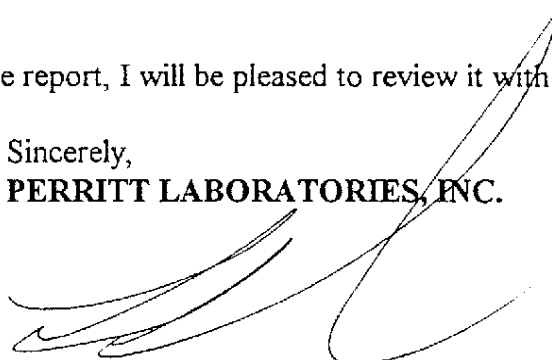
Dear Mr. Gryger,

Herein is our report titled "Evaluation of the 28mm CONTINUOUS THREAD CLOSURE ON A 30ml HDPE ROUND BOTTLE as a Poison Prevention Package with Resecuring Effectiveness for Mold-Rite Plastics Inc."

The test unit was evaluated by using the Consumer Product Safety Commission Protocol and Standards. In the study the test unit fulfills the requirements for Poison Prevention Packaging with resealing effectiveness as per the Code of Federal Regulations (C.F.R.) Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744.

After you have had an opportunity to read the report, I will be pleased to review it with you.

Sincerely,  
**PERRITT LABORATORIES, INC.**



Richard A. Ward  
Director of Consumer Product Testing

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## I. SUMMARY

Report to: Mold-Rite Plastics Inc.  
1 Plant Street, PO Box 160  
Plattsburgh, NY 12901  
Date: July 2, 1997  
Samples of: 28mm CONTINUOUS THREAD CLOSURE ON  
A 30ml HDPE ROUND BOTTLE  
Contract No.: 1206-006  
Samples Received: May 8, 1997  
Submitted by: George Gryger

### Objective

The client submitted the above sample for a study to determine if the unit is in compliance with the Consumer Product Safety Commission (CPSC) protocol and standards for poison prevention packaging with resealing effectiveness as per the Code of Federal Regulations (C.F.R.) Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744.

### Procedures

The protocol for the evaluation of packaging for poison prevention (C.F.R. Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744) was strictly adhered to for this study.

### Panelists

In the course of this study 100 children (42 to 51 months of age) and 100 seniors (50 to 70 year-olds, 70% female) were employed. An additional 100 children were employed to test the packages that the seniors reclosed.

### Results

Results of the study indicate that the 28mm CONTINUOUS THREAD CLOSURE ON A 30ml HDPE ROUND BOTTLE fulfills the standards for poison prevention packaging with resealing effectiveness according to C.F.R. Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744.

Mold-Rite Plastics Inc.  
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July 2, 1997

## II. INTRODUCTION

Mold-Rite Plastics Inc. wished to determine if the 28mm CONTINUOUS THREAD CLOSURE ON A 30ml HDPE ROUND BOTTLE fulfills the Consumer Product Safety Commission's (CPSC) standards and protocols for poison prevention packaging with resealing effectiveness set forth in the Code of Federal Regulations Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744. Perritt Laboratories, Inc., a NAMAS accredited laboratory<sup>1</sup> for testing child-resistant packaging according to the CPSC protocol, was requested to evaluate the packaging using the above protocol.

Perritt Laboratories, Inc., an independent testing laboratory, has been evaluating child-resistant packaging for both industry and government for over twenty years. The company is recognized as the leader in the field by virtue of having employed hundreds of thousands of panelists and evaluated thousands of packaging concepts for child-resistance. Perritt Laboratories, Inc. utilizes standard operating procedures (SOP's), along with quality assurance programs in accordance with good laboratory practices (GLP) for non-clinical laboratories.

In the course of this evaluation, the packaging was tested with panels consisting of 100 seniors (50 to 70 year-olds, 70% female) and 100 children (42 to 51 months of age, evenly distributed) obtained from nursery schools, day care centers and civic groups. An additional 100 children were also employed to test the packages that the seniors reclosed. The data derived from the study were assembled in a meaningful fashion and reviewed to determine whether the packaging met the cited standard for poison prevention packaging with resealing effectiveness presented herein.

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1

Perritt Laboratories, Inc. received its updated NAMAS accreditation (#1457 SIII) for testing packaging for child-resistance according to CPSC's final ruling published in the Federal Register, Vol. 60, No. 140, pp. 37710 to 37744 in August of 1995.

NAMAS is the National Measurement Accreditation Service of the United Kingdom. Organizations accredited by NAMAS meet the requirements of EN 45001, ISO Guide 25 and the relevant requirements of the ISO 9000/EN 29000/BS 5750 series of standards, including those of the model described in ISO 9002/EN 29002/BS 5750 Part 2 when acting as suppliers producing test results.

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### III. PROCEDURE

The following standard and protocol was adhered to in this study.

#### Protocol

Code of Federal Regulations Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744:

#### 1700.20 Testing procedure for testing special packaging.

(a) Test protocols - (1) General requirements - (i) Requirements for packaging. As specified in § 1700.15(b), special packaging is required to meet the child test requirements and the applicable adult test requirements of this § 1700.20.

(ii) Condition of packages to be tested. (A) Tamper-resistant feature. Any tamper-resistant feature of the package to be tested shall be removed prior to testing unless it is part of the package's child-resistant design. Where a package is supplied to the consumer in an outer package that is not part of the package's child-resistant design, one of the following situations applies.

(1) In the child test, the package is removed from the outer package, and the outer package is not given to the child.

(2) In both the adult tests, if the outer package bears instructions for how to open or properly resecure the package, the package shall be given to the test subject in the outer package. The time required to remove the package from the outer packages is not counted in the times allowed for attempting to open and, if appropriate, reclose the package.

(3) In both the adult tests, if the outer package does not bear any instructions relevant to the test, the package will be removed from the outer package, and the outer package is not given to the test subject.

(B) Reclosable packages - adult tests. In both the adult tests, reclosable packages, if assembled by the testing agency, shall be properly secured at least 72 hours prior to beginning the test to allow the materials (e.g., the closure liner) to "take a set." If assembled by the testing agency, torque-dependent closures shall be secured at the same on-torque as applied on the packaging line. Application torques must be recorded in the test report. All packages shall be handled so that no damage or jarring will occur during storage or transportation. The packages shall not be exposed to extreme conditions of heat or cold. The packages shall be tested at room temperature.

(2) Child test - (i) Test subjects. (A) Selection criteria. Use from 1 to 4 groups of 50 children, as required under the sequential testing criteria in table 1. No more than 20 percent of the children in each group shall be tested at or obtained from any given site. Each group of children shall be randomly selected as to age, subject to the limitations set

forth below. Thirty percent of the children in each group shall be of age 42-44 months, 40 percent of the children in each group shall be of age 45-48 months, and 30 percent of the children in each group shall be of age 49-51 months. The children's ages shall be calculated as follows:

(1) Arrange the birth date and test date by the numerical designations for month, day, and year.

(2) Subtract the month, day, year numbers for the birth date from the respective numbers for the test date. This may result in negative numbers for the months or days.

(3) Multiply the difference in years by 12 to obtain the number of months in the difference in years, and add this value to the number of months that was obtained when the birth date was subtracted from the test date. This figure either will remain the same or be adjusted up or down by 1 month, depending on the number of days obtained in the subtraction of the birth date from the test date.

(4) If the number of days obtained by subtracting the days in the birth date from the days in the test date is +16 or more, 1 month is added to the number of months obtained above. If the number of days is -16 or less, subtract 1 month. If the number of days is between -15 and +15 inclusive, no change is made in the number of months.

(B) Gender distribution. The difference between the number of boys and the number of girls in each age range shall not exceed 10 percent of the number of children in that range. The children selected should have no obvious or overt physical or mental handicap. Each child's parent or guardian shall read and sign a consent form prior to the child's participation. (The Commission staff will not disregard the results of tests performed by other parties simply because informed consent for children is not obtained.)

(ii) Test failures. A test failure shall be any child who opens the special packaging or gains access to its contents. In the case of unit packaging, however, a test failure shall be any child who opens or gains access to the number of individual units which constitute the amount that may produce serious personal injury or serious illness, or a child who opens or gains access to more than 8 individual units, whichever number is lower, during the full 10 minutes of testing. The number of units a child opens or gains access to is interpreted as the individual units from which the product has been or can be removed in whole or in part. The determination of the amount of substance that may produce serious personal injury or serious illness shall be based on a 25-pound child. Manufacturers or packagers intending to use unit packaging for a substance requiring special packaging are requested to submit such toxicological data to the Commission's Office of Compliance.

(iii) Sequential test. The sequential test is initially conducted using 50 children, and, depending on the results, the criteria in Table 1 determine whether the package is either child-resistant or not child-resistant or whether further testing is required. Further testing is required if the results are inconclusive and involves the use of one or more additional groups of 50 children each, up to a maximum of 200 children. No individual shall administer the test to more than 30 percent of the children tested in each group. Table 1 gives the acceptance (pass), continue testing, and rejection (fail) criteria to be

TABLE 1. - Number of Openings: Acceptance (Pass), Continue Testing, and Rejection (Fail) Criteria for the First 5 minutes and the Full 10 minutes of the Children's Protocol Test

Test Panel	Cumulative number of children	Package openings					
		First 5 minutes			Full 10 minutes		
		Pass	Continue	Fail	Pass	Continue	Fail
1....	50	0-3	4-10	11+	0-5	6-14	15+
2....	100	4-10	11-18	19+	6-15	16-24	25+
3....	150	11-18	19-25	26+	16-25	26-34	35+
4....	200	19-30	.....	31+	26-40	.....	41+

used for the first 5 minutes and the full 10 minutes of the children's test. If the test continues past the initial 50-child panel, the package openings shown in Table 1 are cumulative.

(iv) Test procedures. The children shall be divided into groups of two. The testing shall be done in a location that is familiar to the children; for example, their customary nursery school or regular kindergarten. No child shall test more than two special packages. When more than one special package is being tested, each package shall be of a different ASTM type and they shall be presented to the paired children in random order. This order shall be recorded. The children shall be tested by the procedure incorporated in the following test instructions:

**Standardized Child Test Instructions**

1. Reclosable packages, if assembled by the testing agency, shall be properly secured at least 72 hours prior to the opening described in instruction number 3 to allow the materials, (e.g. the closure liner), to "take a set." Application torques must be recorded in the test report.

2. All packages shall be handled so that no damage or jarring will occur during storage or transportation. The packages shall not be exposed to extreme conditions of heat or cold. The packages shall be tested at room temperature.

3. Reclosable packages shall be opened and properly resecured one time (or more if appropriate), by the testing agency or other adult prior to testing. The opening and resecuring shall not be done in the presence of the children. (In the adult-resecuring test, the tester must not open and resecure the package prior to the test.) If multiple openings/resecurings are to be used, each of four (4) testers shall open and properly resecure one fourth of the packages once and then shall open and properly resecure each package a second, third, fourth, through tenth (or other specified number) time, in the

same sequence as the first opening and resealing. The packages shall not be opened and resealed again prior to testing. The name of each tester and the package numbers that he/she opens and reseals shall be recorded and reported. It is not necessary for the tester to protocol test the packages that they opened and resealed.

4. The child shall have no overt physical or mental handicaps. No child with a permanent or temporary illness, injury, or handicap that would interfere with his/her effective participation shall be included in the test.

5. The testing shall take place in a well-lighted location that is familiar to the children and that is isolated from all distractions.

6. The tester, or another adult, shall escort a pair of children to the test area. The tester shall seat the two children so that there is no visual barrier between the children and the tester.

7. The tester shall talk to the children to make them feel at ease.

8. The children shall not be given the impression that they are in a race or contest. They are not to be told that the test is a game or that it is fun. They are not to be offered a reward.

9. The tester shall record all data prior to, or after, the test so that full attention can be on the children during the test period.

10. The tester shall use a stopwatch(s) or other timing device to time the number of seconds it takes the child to open the package and to time the 5-minute test periods.

11. To begin the test, the tester shall hand the children identical packages and say, "PLEASE TRY TO OPEN THIS FOR ME."

12. If a child refuses to participate after the test has started, the tester shall reassure the child and gently encourage the child to try. If the child continues to refuse, the tester shall ask the child to hold the package in his/her lap until the other child is finished. This pair of children shall not be eliminated from the results unless the refusing child disrupts the participation of the other child.

13. Each child shall be given up to 5 minutes to open his/her package. The tester shall watch the children at all times during the test. The tester shall minimize conversations with the children as long as they continue to attempt to open their packages. The tester shall not discourage the children verbally or with facial expressions. If a child gets frustrated or bored and stops trying to open his/her package, the tester shall reassure the child and gently encourage the child to keep trying (e.g., "please try to open the package").

14. The children shall be allowed freedom of movement to work on their packages as long as the tester can watch both children (e.g., they can stand up, get down on the floor, or bang or pry the package).

15. If a child is endangering himself or others at any time, the test shall be stopped and the pair of children eliminated from the final results.

16. The children shall be allowed to talk to each other about opening the packages and shall be allowed to watch each other try to open the packages.

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17. A child shall not be allowed to try to open the other child's package.

18. If a child opens his/her package, the tester shall say, "THANK YOU," take the package from the child and put it out of the child's reach. The child shall not be asked to open the package a second time.

19. At the end of the 5-minute period, the tester shall demonstrate how to open the package if either child has not opened his or her package. A separate "demo" package shall be used for the demonstration.

20. Prior to beginning the demonstration, the tester shall ask the children to set their packages aside. The children shall not be allowed to continue to try to open their packages during the demonstration period.

21. The tester shall say, "WATCH ME OPEN MY PACKAGE."

22. Once the tester gets the children's full attention, the tester shall hold the demo package approximately two feet from the children and open the package at a normal speed as if the tester were going to use the contents. There shall be no exaggerated opening movements.

23. The tester shall not discuss or describe how to open the package.

24. To begin the second 5-minute period, the tester shall say, "NOW YOU TRY TO OPEN YOUR PACKAGES."

25. If one or both children have not used their teeth to try to open their packages during the first 5 minutes, the tester shall say immediately before beginning the second 5-minute period, "YOU CAN USE YOUR TEETH IF YOU WANT TO." This is the only statement that the tester shall make about using teeth.

26. The test shall continue for an additional 5 minutes or until both children have opened their packages, whichever comes first.

27. At the end of the test period, the tester shall say, "THANK YOU FOR HELPING." If children were told that they could use their teeth, the tester shall say, "I KNOW I TOLD YOU THAT YOU COULD USE YOUR TEETH TODAY, BUT YOU SHOULD NOT PUT THINGS LIKE THIS IN YOUR MOUTH AGAIN." In addition, the tester shall say, "NEVER OPEN PACKAGES LIKE THIS WHEN YOU ARE BY YOURSELF. THIS KIND OF PACKAGE MIGHT HAVE SOMETHING IN IT THAT WOULD MAKE YOU SICK."

28. The children shall be escorted back to their classroom or other supervised area by the tester or another adult.

29. If the children are to participate in a second test, the tester shall have them stand up and stretch for a short time before beginning the second test. The tester shall take care that the children do not disrupt other tests in progress.

(3) Senior-adult panel - (i) Test subjects. Use a group of 100 senior adults. Not more than 24 percent of the senior adults tested shall be obtained from or tested at any one site. Each group of senior adults shall be randomly selected as to age, subject to the limitations set forth below. Twenty-five percent of the participants shall be 50-54 years of age, 25% of participants shall be 55-59 years of age, and 50% of the participants shall be

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60-70 years old. Seventy percent of the participants of ages 50-59 and ages 60-70 shall be female (17 or 18 females shall be apportioned to the 50-54 year age group). No individual tester shall administer the test to more than 35% of the senior adults tested. The adults selected should have no obvious or overt physical or mental disability.

(ii) Screening procedures. Participants who are unable to open the packaging being tested in the first 5-minute time period, are given a screening test. The screening tests for this purpose shall use two packages with conventional (not child-resistant (CR) or "special") closures. One closure shall be a plastic snap closure and the other a CT plastic closure. Each closure shall have a diameter of 28 mm  $\pm$  18%, and the CT closures shall have been resecured 72 hours before testing at 10 inch-pounds of torque. The containers for both the snap- and Ct-type closures shall be round plastic containers, in sizes of 2 ounce  $\pm$  ½ ounce for the CT-type closure and 8 drams  $\pm$  4 drams for the snap-type closure. Persons who cannot open and close both of the screening packages in 1-minute screening tests shall not be counted as participants in the senior-adult panel.

(iii) SAUE. The senior adult use effectiveness (SAUE) is the percentage of adults who both opened the package in the first (5-minute) test period and opened and (if appropriate) properly resecured the package in the 1-minute test period.

(iv) Test procedures. The senior adults shall be tested individually, rather than in groups of two or more. The senior adults shall receive only such printed instructions on how to open and properly secure the special packaging as will appear on or accompany the package as it is delivered to the consumer. The senior-adult panel is tested according to the procedure incorporated in the following senior-adult panel test instructions:

### **Test Instructions for Senior Test**

The following test instructions are used for all senior tests. If non-reclosable packages are being tested, the commands to close the package are eliminated.

1. No adult with a permanent or temporary illness, injury, or disability which would interfere with his/her effective participation shall be included in the test.

2. Each adult shall read and sign a consent form prior to participating. Any appropriate language from the consent form may be used to recruit potential participants. The form shall include the basic elements of informed consent as defined in 16 CFR 1028.116. Before beginning the test, the tester shall say, "PLEASE READ AND SIGN THIS CONSENT FORM." If an adult cannot read the consent form for any reason (forgot glasses, illiterate, etc.), he/she shall not participate in the test.

3. Each adult shall participate individually and not in the presence of other participants or onlookers.

4. The tests shall be conducted in well-lighted and distraction-free areas.

5. Records shall be filled in before or after the test, so that the tester's full attention is on the participant during the test period. Recording the test times to open and resecure the packages are the only exceptions.

6. To begin the first 5-minute test period, the tester says, "I AM GOING TO ASK YOU TO OPEN AND PROPERLY CLOSE THESE TWO IDENTICAL PACKAGES ACCORDING TO THE INSTRUCTIONS FOUND ON THE CAP." (Specify other instruction locations if appropriate.)

7. The first package is handed to the participant by the tester, who says, "PLEASE OPEN THIS PACKAGE ACCORDING THE DIRECTIONS OF THE CAP." (Specify other instruction locations if appropriate.) If the package contains product, the tester shall say, "PLEASE EMPTY THE (PILLS, TABLETS, CONTENTS, ETC.) INTO THIS CONTAINER." After the participant opens the package, the tester says, "PLEASE CLOSE THE PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS OF THE CAP." (Specify other instruction locations if appropriate)

8. Participants are allowed up to 5 minutes to read the instructions and open and close the package. The tester uses a stopwatch(s) or other timing device to time the opening and resealing times. The elapsed times in seconds to open the package and to close the package are recorded on the data sheet as two separate times.

9. After 5 minutes, or when the participant has opened and closed the package, whichever comes first, the tester shall take all test materials from the participant. The participant may remove and replace the closure more than once if the participant initiates these actions. If the participant does not open the package and stops trying to open it before the end of the 5-minute period, the tester shall say, "ARE YOU FINISHED WITH THAT PACKAGE, OR WOULD YOU LIKE TO TRY AGAIN?" If the participant indicates that he/she is finished or cannot open the package and does not wish to continue trying, skip to Instruction 13.

10. To begin the second test period, the tester shall give the participant another, but identical, package and say, "THIS IS AN IDENTICAL PACKAGE. PLEASE OPEN IT ACCORDING TO THE INSTRUCTIONS ON THE CAP." (Specify other instruction locations if appropriate.) If the package contains product, the tester shall say, "PLEASE EMPTY THE (PILLS, TABLETS, CONTENTS, ETC.) INTO THIS CONTAINER." After the participant opens the package, the tester says, "PLEASE CLOSE THIS PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS ON THE CAP." (Specify other instruction locations if appropriate.)

11. The participants are allowed up to 1 minute (60 full seconds) to open and close the package. The elapsed times in seconds to open and to close the package are recorded on the data sheet as two separate times. The time that elapses between the opening of the package and the end of the instruction to close the package is not counted as part of the 1-minute test time.

12. After the 1-minute test, or when the participant has opened and closed the package, whichever comes first, the tester shall take all the test materials from the participant. The participant shall not be allowed to handle the package again. If the participant does not open the package and stops trying to open it before the end of the 1-minute period, the tester shall say, "ARE YOU FINISHED WITH THAT PACKAGE, OR WOULD YOU LIKE TO TRY AGAIN?" If the participant indicates that he/she is finished or cannot open the package and does not wish to continue trying, this shall be counted as a failure of the 1-minute test.

13. Participants who do not open the package in the first 5-minute test period are asked to open and close two non-child-resistant screening packages. The participants are given a 1-minute test period for each package. The tester shall give the participant a package and say, "PLEASE OPEN AND PROPERLY CLOSE THIS PACKAGE." The tester records the time for opening and closing, or 61 seconds, whichever is less, on the data sheet. The tester then gives the participant the second package and says, "PLEASE OPEN AND PROPERLY CLOSE THIS PACKAGE." The times to open and resecure or 61 seconds, whichever is less, shall be recorded on the data sheet.

14. Participants who cannot open and resecure both of the non-child-resistant screening packages are not counted as part of the 100-senior panel. Additional participants are selected and tested.

15. No adult may participate in more than two tests per sitting. If a person participates in two tests, the packages tested shall not be the same ASTM type of package.

16. If more adults in a sex or age group are tested than are necessary to determine SAUE, the last person(s) tested shall be eliminated from that group.

(4) Younger-adult panel. (i) One hundred adults, age 18 to 45 inclusive, with no overt physical or mental handicaps, and 70 percent of whom are female, shall comprise the test panel for younger adults. Not more than 35% of adults shall be obtained or tested at any one site. No individual tester shall administer the test to more than 35% of the adults tested. The adults shall be tested individually, rather than in groups of two or more. The adults shall receive only such printed instructions on how to open and properly resecure the special packaging as will appear on the package as it is delivered to the consumer. Five minutes shall be allowed to complete the opening and, if appropriate, the resealing process.

(ii) Records shall be kept of the number of adults unable to open and of the number of the other adults tested who fail to properly resecure the special packaging. The number adults who successfully open the special packaging and then properly resecure the special packaging (if resealing is appropriate) is the percent of adult-use effectiveness of the special packaging. In the case of unit packaging, the percent of adult-use effectiveness shall be the number of adults who successfully open a single(unit) package.

(iii) Adult-use effectiveness of not less than 90 percent.

#### **Adult-Resecuring Procedure**

1. After the adult participant in either the senior-adult test of 16 CFR 1700.20(a)(3) or the younger-adult test of 16 CFR 1700.20(a)(4) has resealed the package, or at the end of the test period (whichever comes first), the tester shall take the package and place it out of reach. The adult participant shall not be allowed to handle the package again.

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2. The packages that have been opened and appear to be resecured by adults shall be tested by children according the child-test procedures to determine if the packages have been properly resecured. The packages are given to the children without being opened or resecured again for any purpose.

3. Using the results of the adult tests and the tests of apparently-secured package by children, the adult use effectiveness is calculated as follows:

a. Adult use effectiveness.

1. The number of adult opening and resealing failures, plus the number of packages that were opened by the children during the full 10-minute test that exceeds 20% of the apparently-secured packages, equals the total number of failures.

2. The total number of packages tested by adults (which is 100) minus the total number of failures equals the percent adult-use effectiveness.

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### The Package

The test package was the 28mm CONTINUOUS THREAD CLOSURE ON A 30ml HDPE ROUND BOTTLE. For purposes of this test, all of the units tested were empty and received assembled at 10 Inch Pounds of Torque. Directions to open the package read: OPEN: PUSH DOWN & TURN---CLOSE TIGHTLY. A picture of the package appears in Figure 1 of this report.

### Panelists

In the child testing phase of this study, 100 children between the ages of 42 and 51 months distributed into three age groups (42-44, 45-48, and 49-51 months, evenly distributed by sex) were employed.

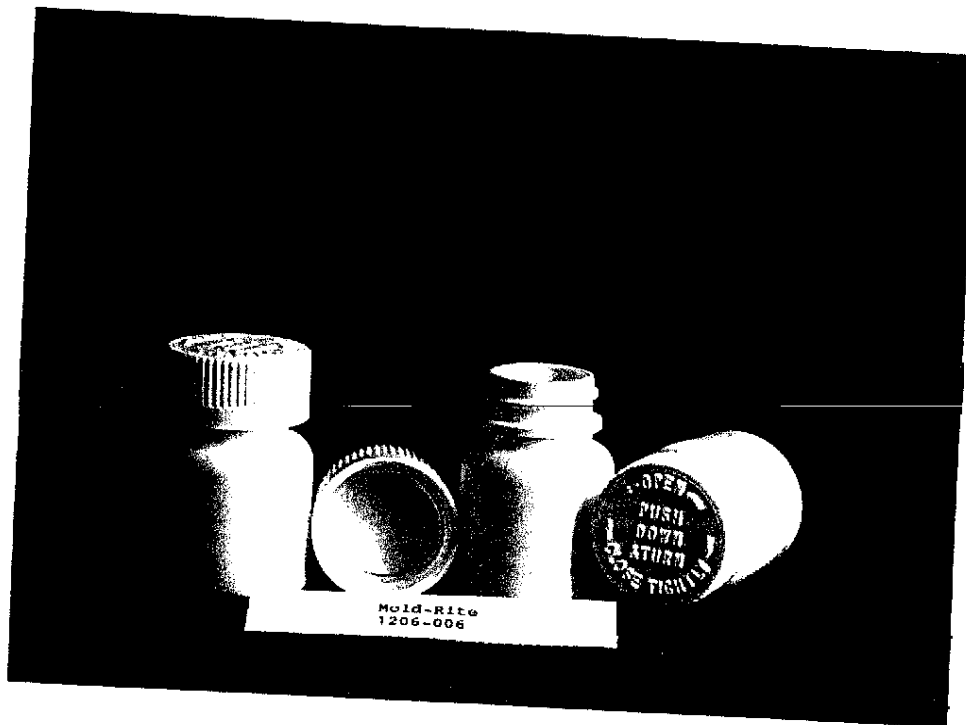
Seniors (100) employed in the study also satisfied the requirements of the protocol, with ages ranging from 50 to 70 years of age divided into three age groups (50-54, 55-59, and 60-70 years old with 70% female).

An additional 100 children were employed to determine if the senior-adult panelists properly closed the packages.

### Test supervisor(s)

Test supervisor(s) were instructed to conduct the evaluation of the packaging in strict accordance with the C.F.R. Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744. To ensure these procedures were adhered to, our complete quality system was followed, including periodic observations throughout the package evaluation.

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28mm CONTINUOUS THREAD CLOSURE  
ON A 30ml HDPE ROUND BOTTLE  
Figure 1

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#### IV. RESULTS AND DISCUSSION

Results of this study appear in the tables section of the report. These tables represent a compilation of all data obtained during the study. For clarity in presentation and discussion of this information, the following features will be used as the major points of discussion:

- \* Child-resistant effectiveness
- \* Senior-use effectiveness
- \* Senior-resecuring use effectiveness
- \* Meeting C.F.R. Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744.

##### Child-resistant effectiveness

Results of the package evaluation by the 100 child panelists appear in Table 1 of the report. From this table it will be noted that 7 children were successful in opening the packaging before demonstration and 1 child was successful in opening the packaging following a demonstration for a total of 8 successful child panelists. This represents a child-resistant effectiveness of 92%.

##### Senior-use effectiveness

The senior panel consisted of 70 females and 30 males. Results of the senior test appear in Table 2 of this report. A total of 25 of the 25 seniors in the 50 to 54 year old age group were successful in opening the first package and opening and properly closing the second package, 25 of the 25 seniors in the 55 to 59 year old age group were successful, and 50 of the 50 seniors were successful in the 60 to 70 year old age group. The SAUE was calculated at 100 minus 0 for a final SAUE, including the resealing test, of 100 for the 100 seniors and 100 children who tested the packages apparently resealed by the seniors. The exact opening and closing times are given in the Senior Test Packaging Data.

##### Senior-resealing use effectiveness

A group of 100 children were employed to test the packages that were apparently resealed by the senior-adults. Results of the senior-resealing test with children appear in Table 3 of this report. A total of 17 children were successful in opening the apparently resealed packages. The amount over 20% ( $100 \times .2 = 20$ ) is 0, and is subtracted from the calculated senior-use effectiveness.

Meeting C.F.R. Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744.

The 28mm CONTINUOUS THREAD CLOSURE ON A 30ml HDPE ROUND BOTTLE fulfills the standards for poison prevention packaging with resealing effectiveness according to C.F.R. Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744.

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## V. CONCLUSION

The data presented in the report demonstrates that the 28mm CONTINUOUS THREAD CLOSURE ON A 30ml HDPE ROUND BOTTLE fulfills the requirements for poison prevention packaging with resealing effectiveness according to the Code of Federal Regulations Title 16, Part 1700, with final rule changes cited in the Federal Register, Vol. 60, No. 140, Friday, July 21, 1995, pp. 37710 to 37744.

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Evaluation of the 28mm CONTINUOUS THREAD CLOSURE ON A 30ml  
 HDPE ROUND BOTTLE as a child-resistant package for Mold-Rite Plastics Inc..

Table 1. Package opening test evaluated by children 42 to 51  
 months of age for child-resistant effectiveness.

<u>Age in Months</u>				<u>Successful Panelists</u>				<u>Total</u>
	<u>M</u>	<u>F</u>	<u>Total</u>	<u>Before Demo.</u>		<u>After Demo.</u>		
	<u>M</u>	<u>F</u>	<u>Total</u>	<u>M</u>	<u>F</u>	<u>M</u>	<u>F</u>	
42-44	15	15	30	0	1	0	0	1
45-48	20	20	40	2	1	0	0	3
49-51	15	15	30	0	3	1	0	4
<b>Totals</b>	<b>50</b>	<b>50</b>	<b>100</b>	<b>2</b>	<b>5</b>	<b>1</b>	<b>0</b>	<b>8</b>

**CHILD-RESISTANT EFFECTIVENESS = 92%**

## CHILD TEST - PACKAGE DATA

CLIENT NAME: Mold-Rite Plastics Inc.  
 DESCRIPTION: 28mm C.T./30ml HDPE  
 CONTRACT NO. 1206-006

July 2, 1997

PACKAGE NUMBER	TEST DATE	SITE CODE	INTER- VIEWER	BIRTH DATE	AGE MON.	SEX	OPENING SECONDS 601=NOT OPENED	METHOD
1	5/12/97	C853	12	3/29/93	49	F	601	0
2	5/12/97	C853	12	4/11/93	49	M	601	0
3	5/12/97	C503	14	11/16/93	42	M	601	0
4	5/12/97	C503	14	10/15/93	43	M	601	0
5	5/12/97	C503	14	3/31/93	49	M	601	0
6	5/12/97	C503	14	4/02/93	49	F	601	0
7	5/12/97	C853	12	1/28/93	51	M	601	0
8	5/12/97	C853	12	10/31/93	42	M	601	0
9	5/12/97	C853	12	1/28/93	51	F	601	0
10	5/12/97	C853	12	11/16/93	42	M	601	0
11	5/12/97	C503	14	9/08/93	44	F	601	0
12	5/12/97	C503	14	8/06/93	45	F	601	0
13	5/13/97	C853	17	7/17/93	46	F	601	0
14	5/13/97	C853	17	7/21/93	46	F	601	0
15	5/13/97	C853	17	9/12/93	44	M	601	0
16	5/13/97	C853	17	1/29/93	51	F	601	0
17	5/13/97	C503	16	8/12/93	45	M	601	0
18	5/13/97	C503	16	6/08/93	47	F	601	0
19	5/13/97	C503	16	3/03/93	50	M	601	0
20	5/13/97	C503	16	3/18/93	50	M	601	0
21	5/14/97	C800	12	10/12/93	43	M	601	0
22	5/14/97	C800	12	5/13/93	48	M	601	0
23	5/14/97	C800	14	2/03/93	51	M	601	0
24	5/14/97	C800	14	2/22/93	51	M	601	0
25	5/14/97	C773	14	6/22/93	47	M	601	0
26	5/14/97	C773	14	7/02/93	46	F	601	0
27	5/14/97	C773	12	4/19/93	49	M	328	3
28	5/14/97	C773	12	1/31/93	51	F	245	3
29	5/14/97	C773	12	6/05/93	47	M	601	0
30	5/14/97	C773	12	5/28/93	48	F	26	3
31	5/14/97	C773	14	10/17/93	43	F	601	0
32	5/14/97	C773	14	9/17/93	44	F	601	0
33	5/14/97	C773	12	8/20/93	45	F	601	0
34	5/14/97	C773	12	6/09/93	47	F	601	0
35	5/14/97	C800	12	3/05/93	50	F	125	3
36	5/14/97	C800	12	3/29/93	50	F	601	0
37	5/14/97	C800	14	5/11/93	48	M	601	0
38	5/14/97	C800	14	6/09/93	47	M	601	0
39	5/15/97	C761	17	6/27/93	47	M	601	0
40	5/15/97	C761	17	11/02/93	42	F	601	0
41	5/15/97	C761	17	10/01/93	43	F	110	1
42	5/15/97	C761	17	11/04/93	42	M	601	0
43	5/16/97	C694	16	7/08/93	46	F	601	0
44	5/16/97	C694	16	8/18/93	45	F	601	0
45	5/16/97	C694	16	9/12/93	44	F	601	0
46	5/16/97	C694	16	5/21/93	48	M	601	0
47	5/16/97	C694	16	11/08/93	42	F	601	0
48	5/16/97	C694	16	11/08/93	42	F	601	0
49	5/20/97	C692	16	5/21/93	48	M	601	0
50	5/20/97	C692	16	5/31/93	48	M	601	0

## CHILD TEST - PACKAGE DATA

CLIENT NAME: Mold-Rite Plastics Inc.  
 DESCRIPTION: 28mm C.T./30ml HDPE  
 CONTRACT NO. 1206-006

July 2, 1997

PACKAGE NUMBER	TEST DATE	SITE CODE	INTER- VIEWER	BIRTH DATE	AGE MON.	SEX	OPENING SECONDS	
							601=NOT OPENED	METHOD
51	6/12/97	C514	12	3/03/93	51	M	601	0
52	6/12/97	C514	12	3/30/93	50	M	601	0
53	6/12/97	C514	14	7/27/93	47	M	601	0
54	6/12/97	C514	14	9/09/93	45	F	601	0
55	6/12/97	C514	14	6/23/93	48	M	87	3
56	6/12/97	C514	14	4/29/93	49	F	601	0
57	6/12/97	C514	12	7/19/93	47	F	601	0
58	6/12/97	C514	12	5/27/93	49	M	601	0
59	6/12/97	C514	12	2/28/93	51	F	601	0
60	6/12/97	C514	12	7/15/93	47	M	183	6
61	6/16/97	C061	12	11/20/93	43	M	601	0
62	6/16/97	C061	12	3/26/93	51	F	601	0
63	6/17/97	C064	14	7/20/93	47	F	601	0
64	6/17/97	C064	14	7/14/93	47	F	601	0
65	6/17/97	C525	12	9/03/93	45	F	601	0
66	6/17/97	C525	12	7/30/93	47	M	601	0
67	6/17/97	C525	12	3/08/93	51	M	601	0
68	6/17/97	C525	12	3/23/93	51	F	601	0
69	6/17/97	C064	14	4/08/93	50	F	601	0
70	6/17/97	C064	14	5/03/93	49	F	98	3
71	6/16/97	C629	16	6/17/93	48	M	601	0
72	6/16/97	C629	16	7/13/93	47	M	601	0
73	6/16/97	C629	16	5/20/93	49	M	601	0
74	6/16/97	C629	16	6/12/93	48	M	601	0
75	6/16/97	C629	16	9/17/93	45	M	601	0
76	6/16/97	C629	16	8/13/93	46	F	601	0
77	6/16/97	C629	16	6/14/93	48	M	601	0
78	6/16/97	C629	16	7/04/93	47	F	601	0
79	6/16/97	C629	16	11/18/93	43	M	601	0
80	6/16/97	C629	16	10/01/93	44	F	601	0
81	6/17/97	C064	14	9/07/93	45	M	601	0
82	6/17/97	C064	14	10/04/93	44	F	601	0
83	6/17/97	C525	12	9/21/93	45	F	601	0
84	6/17/97	C525	12	10/02/93	44	M	601	0
85	6/17/97	C064	14	10/16/93	44	M	601	0
86	6/17/97	C064	14	11/19/93	43	M	601	0
87	6/17/97	C525	12	11/22/93	43	M	601	0
88	6/17/97	C525	12	10/18/93	44	F	601	0
89	6/17/97	C064	14	12/16/93	42	M	601	0
90	6/17/97	C064	14	5/20/93	49	F	601	0
91	6/17/97	C525	12	12/06/93	42	F	601	0
92	6/17/97	C525	12	11/26/93	43	M	601	0
93	6/18/97	C841	16	7/03/93	47	F	601	0
94	6/18/97	C841	16	5/02/93	50	F	601	0
95	6/20/97	C546	14	5/04/93	50	M	601	0
96	6/20/97	C546	14	10/11/93	44	F	601	0
97	6/23/97	C538	16	8/15/93	46	F	601	0
98	6/23/97	C538	16	11/05/93	44	F	601	0
99	6/23/97	C538	16	11/23/93	43	F	601	0
100	6/23/97	C538	16	3/15/93	51	M	601	0

Evaluation of the 28mm CONTINUOUS THREAD CLOSURE ON A 30ml  
 HDPE ROUND BOTTLE for senior-use effectiveness for Mold-Rite Plastics Inc..

Table 2. Package opening test evaluated by adults 50 to  
 70 years of age for senior-use effectiveness.

	<u>Panelists Tested</u>	<u>Successful Panelists</u>	
		<u>First Opening</u>	<u>Second Opening and Second Closing</u>
<u>50 - 54 years old:</u>			
Female	18	18	18
Male	7	7	7
<b>Subtotal</b>	<b>25</b>	<b>25</b>	<b>25</b>
<u>55 - 59 years old:</u>			
Female	17	17	17
Male	8	8	8
<b>Subtotal</b>	<b>25</b>	<b>25</b>	<b>25</b>
<u>60 - 70 years old:</u>			
Female	35	35	35
Male	15	15	15
<b>Subtotal</b>	<b>50</b>	<b>50</b>	<b>50</b>

SENIOR-USE EFFECTIVENESS (SAUE) = 100 - 0 = 100%

SENIOR TEST PACKAGE DATA

CLIENT NAME: Mold-Rite Plastics Inc.  
 DESCRIPTION: 28mm C.T./30ml HDPE  
 CONTRACT NO. 1206-006

July 2, 1997

PACKAGE NUMBER	TEST DATE	SITE CODE	INTER-VIEWER	SEX	AGE	FIRST OPENING FAIL = 301 SEC	FIRST CLOSING STOP = 301 SEC	SECOND OPENING FAIL = 61 SEC	SECOND CLOSING FAIL = 61 SEC
1	5/12/97	C994	16	F	59	3	2	3	2
2	5/12/97	C994	16	F	68	6	2	4	2
3	5/12/97	C994	16	F	54	4	2	3	2
4	5/12/97	C994	16	M	52	4	2	4	3
5	5/12/97	C994	16	M	60	8	3	4	3
6	5/12/97	C994	16	M	60	10	3	8	3
7	5/12/97	C994	16	F	52	6	2	4	2
8	5/12/97	C994	16	F	66	7	3	4	2
9	5/12/97	C994	16	M	59	4	2	5	2
10	5/12/97	C994	16	F	53	4	2	4	2
11	5/12/97	C994	16	M	65	7	3	4	3
12	5/12/97	C994	16	F	60	5	3	4	2
13	5/12/97	C994	16	M	61	7	3	4	2
14	5/12/97	C994	16	F	61	4	2	5	2
15	5/12/97	C994	16	M	53	7	2	4	2
16	5/12/97	C994	16	F	50	6	2	3	2
17	5/12/97	C994	16	M	54	4	1	2	1
18	5/12/97	C994	16	M	55	7	2	6	2
19	5/12/97	C994	16	F	59	4	3	4	2
20	5/12/97	C994	16	F	66	7	3	6	3
21	5/12/97	C994	16	F	67	8	3	6	3
22	5/12/97	C994	16	F	60	4	2	4	2
23	5/12/97	C994	16	M	63	3	2	3	2
24	5/12/97	C994	16	M	56	6	3	5	3
25	5/14/97	C967	17	M	53	5	2	4	2
26	5/14/97	C967	17	F	50	6	2	3	2
27	5/14/97	C967	17	F	56	4	2	4	2
28	5/14/97	C967	17	F	67	9	3	6	2
29	5/14/97	C967	17	M	67	5	2	5	2
30	5/14/97	C967	17	F	53	4	2	3	2
31	5/14/97	C967	17	F	65	3	2	3	2
32	5/14/97	C967	17	F	63	7	2	4	2
33	5/14/97	C967	17	F	63	8	3	4	3
34	5/14/97	C967	17	F	62	4	2	4	2
35	5/14/97	C967	17	F	61	5	3	4	2
36	5/14/97	C967	17	M	56	4	2	4	1
37	5/14/97	C967	17	F	62	8	3	6	3
38	5/14/97	C967	17	F	59	4	2	4	2
39	5/14/97	C967	17	M	57	8	2	4	2
40	5/14/97	C967	17	F	61	7	3	5	2
41	5/14/97	C967	17	F	50	5	2	4	2
42	5/14/97	C967	17	M	52	6	3	5	2
43	5/14/97	C967	17	F	53	8	4	6	2
44	5/14/97	C967	17	M	68	7	3	4	2
45	5/14/97	C967	17	F	56	6	3	4	2
46	5/14/97	C967	17	F	63	4	2	4	2
47	5/14/97	C967	17	F	55	3	2	3	2
48	5/14/97	C967	17	F	56	5	3	4	3
49	5/16/97	C947	12	F	69	2	0	3	4
50	5/16/97	C947	14	M	69	3	1	4	3
51	5/16/97	C947	14	M	63	7	3	2	1

SENIOR TEST PACKAGE DATA

CLIENT NAME: Mold-Rite Plastics Inc.  
 DESCRIPTION: 28mm C.T./30ml HDPE  
 CONTRACT NO. 1206-006

July 2, 1997

PACKAGE NUMBER	TEST DATE	SITE CODE	INTER-VIEWER	SEX	AGE	FIRST OPENING FAIL = 301 SEC	FIRST CLOSING STOP = 301 SEC	SECOND OPENING FAIL = 61 SEC	SECOND CLOSING FAIL = 61 SEC
52	5/16/97	C947	12	F	69	16	6	3	2
53	5/16/97	C947	14	F	65	8	2	4	4
54	5/16/97	C947	12	M	70	2	2	1	2
55	5/16/97	C947	14	F	69	7	2	5	3
56	5/16/97	C947	12	F	68	9	5	4	4
57	5/16/97	C947	14	M	66	19	3	5	4
58	5/16/97	C947	12	F	70	5	3	3	3
59	5/16/97	C947	14	M	66	5	3	2	2
60	5/16/97	C947	12	F	64	5	3	3	3
61	5/16/97	C947	14	M	62	2	2	1	14
62	5/16/97	C947	12	F	68	6	3	15	5
63	5/19/97	C997	14	M	52	4	2	2	1
64	5/19/97	C997	14	M	58	4	1	2	1
65	5/19/97	C997	14	F	50	1	1	1	1
66	5/19/97	C997	14	F	56	1	2	1	1
67	5/19/97	C997	14	M	66	2	2	1	14
68	5/19/97	C997	14	M	66	6	3	9	2
69	5/19/97	C997	14	M	54	8	1	3	1
70	5/19/97	C997	14	F	53	11	4	4	2
71	5/19/97	C997	14	F	51	5	4	1	13
72	5/19/97	C997	14	M	57	5	1	2	1
73	5/19/97	C997	14	F	56	3	1	3	1
74	5/28/97	C995	1	F	69	6	2	4	2
75	5/28/97	C995	1	F	66	4	2	4	2
76	5/28/97	C995	1	F	69	8	3	4	3
77	5/28/97	C995	1	F	70	6	3	5	3
78	5/28/97	C995	1	F	51	9	2	6	2
79	5/28/97	C995	1	F	68	7	2	4	2
80	5/28/97	C995	1	F	66	4	2	4	2
81	5/28/97	C995	1	F	52	6	3	4	3
82	5/28/97	C995	1	F	52	5	3	5	2
83	5/28/97	C995	1	F	57	4	3	4	2
84	5/28/97	C995	1	F	70	10	2	6	2
85	5/28/97	C995	1	F	69	4	2	4	2
86	5/28/97	C995	1	F	57	8	3	7	3
87	5/28/97	C995	1	F	63	4	2	3	2
88	5/28/97	C995	1	F	61	6	3	5	3
89	5/28/97	C995	1	F	66	8	4	7	2
90	5/28/97	C995	1	F	55	6	2	4	2
91	5/28/97	C995	1	F	56	3	2	3	2
92	5/28/97	C995	1	F	53	6	2	4	2
93	5/28/97	C995	1	F	51	4	2	4	2
94	5/28/97	C995	16	F	50	4	2	4	2
95	5/28/97	C995	16	F	50	3	2	4	2
96	5/28/97	C995	16	M	55	6	2	4	2
97	5/28/97	C995	16	F	55	7	2	6	2
98	6/02/97	C975	16	F	55	6	2	4	2
99	6/02/97	C975	16	F	55	4	2	4	2
100	6/02/97	C975	16	F	56	6	3	4	2

Mold-Rite Plastics Inc.  
 1206-006  
 July 2, 1997

Evaluation of the 28mm CONTINUOUS THREAD CLOSURE ON A 30ml HDPE ROUND BOTTLE as a child-resistant package for Mold-Rite Plastics Inc..

Table 3. Senior-resecured package opening test evaluated by children 42 to 51 months of age for senior-resecuring effectiveness.

Age in Months			<u>Total</u>	<u>Successful Panelists</u>				<u>Total</u>
	<u>M</u>	<u>F</u>		Before Demo.		After Demo.		
	<u>M</u>	<u>F</u>		<u>M</u>	<u>F</u>	<u>M</u>	<u>F</u>	
42-43	15	15	30	1	4	0	0	5
45-48	20	20	40	5	1	1	0	7
49-51	15	15	30	3	2	0	0	5
<b>Totals</b>	<b>50</b>	<b>50</b>	<b>100</b>	<b>9</b>	<b>7</b>	<b>1</b>	<b>0</b>	<b>17</b>

The amount over 20% ( $100 \times .2 = 20$ ) is 0, and is subtracted from the calculated senior-use effectiveness.

## CHILD TEST - PACKAGE DATA

CLIENT NAME: Mold-Rite Plastics Inc.  
 DESCRIPTION: Senior-resecured  
 CONTRACT NO. 1206-006

July 2, 1997

PACKAGE NUMBER	TEST DATE	SITE CODE	INTER- VIEWER	BIRTH DATE	AGE MON.	SEX	OPENING	METHOD
							SECONDS 601=NOT OPENED	
1	5/13/97	C853	17	7/16/93	46	M	601	0
2	5/13/97	C853	17	9/24/93	44	F	601	0
3	5/13/97	C853	17	5/08/93	48	M	601	0
4	5/13/97	C853	17	5/14/93	48	F	601	0
5	5/13/97	C853	17	7/10/93	46	F	601	0
6	5/13/97	C853	17	4/22/93	49	M	601	0
7	5/13/97	C853	17	10/10/93	43	F	210	1
8	5/13/97	C853	17	7/16/93	46	F	601	0
9	5/13/97	C853	17	2/09/93	51	M	601	0
10	5/13/97	C853	17	10/11/93	43	M	601	0
11	5/13/97	C503	16	3/22/93	50	M	601	0
12	5/13/97	C503	16	3/19/93	50	M	116	1
13	5/13/97	C503	16	1/29/93	51	F	601	0
14	5/13/97	C503	16	1/29/93	51	M	601	0
15	5/13/97	C503	16	7/15/93	46	M	601	0
16	5/13/97	C503	16	8/26/93	45	F	601	0
17	5/13/97	C503	16	2/04/93	51	F	201	1
18	5/13/97	C503	16	8/01/93	45	M	601	0
19	5/13/97	C503	16	7/03/93	46	F	601	0
20	5/13/97	C503	16	7/21/93	46	F	601	0
21	5/15/97	C761	16	4/29/93	49	F	601	0
22	5/15/97	C761	16	8/20/93	45	M	130	1
23	5/15/97	C761	16	5/07/93	48	M	601	0
24	5/15/97	C761	16	2/09/93	51	M	601	0
25	5/15/97	C761	16	3/19/93	50	M	601	0
26	5/15/97	C761	16	3/08/93	50	M	601	0
27	5/15/97	C761	16	8/17/93	45	F	601	0
28	5/15/97	C761	16	7/19/93	46	M	601	0
29	5/15/97	C761	16	10/15/93	43	M	601	0
30	5/15/97	C761	16	11/01/93	42	M	601	0
31	5/20/97	C692	17	7/29/93	46	F	601	0
32	5/20/97	C692	17	7/29/93	46	F	601	0
33	5/20/97	C692	17	9/20/93	44	M	601	0
34	5/20/97	C692	17	10/24/93	43	F	601	0
35	5/20/97	C692	17	10/08/93	43	M	601	0
36	5/20/97	C692	17	7/24/93	46	M	119	1
37	5/20/97	C692	17	4/10/93	49	F	601	0
38	5/20/97	C692	17	10/04/93	44	M	601	0
39	5/20/97	C692	17	11/01/93	43	F	601	0
40	5/20/97	C692	17	8/11/93	45	F	601	0
41	5/20/97	C692	16	5/28/93	48	M	601	0
42	5/20/97	C692	16	8/14/93	45	F	601	0
43	5/20/97	C692	16	8/06/93	45	M	601	0
44	5/20/97	C692	16	4/20/93	49	F	601	0
45	5/20/97	C692	16	3/24/93	50	M	601	0
46	5/20/97	C692	16	2/05/93	51	M	601	0
47	5/20/97	C692	16	5/17/93	48	F	601	0
48	5/20/97	C692	16	3/14/93	50	F	601	0
49	5/20/97	C692	16	8/10/93	45	F	601	0
50	5/20/97	C692	16	4/08/93	49	M	601	0

## CHILD TEST - PACKAGE DATA

CLIENT NAME: Mold-Rite Plastics Inc.  
 DESCRIPTION: Senior-resecured  
 CONTRACT NO. 1206-006

July 2, 1997

PACKAGE NUMBER	TEST DATE	SITE CODE	INTER- VIEWER	BIRTH DATE	AGE MON.	SEX	OPENING SECONDS 601=NOT OPENED	METHOD
51	5/21/97	C852	14	8/08/93	45	M	601	0
52	5/21/97	C852	14	10/19/93	43	F	601	0
53	5/21/97	C852	14	11/05/93	43	M	271	3
54	5/21/97	C852	14	10/22/93	43	F	227	3
55	5/23/97	C822	14	7/07/93	47	M	601	0
56	5/23/97	C822	14	10/09/93	43	M	601	0
57	5/23/97	C822	14	9/19/93	44	F	601	0
58	5/23/97	C822	14	6/01/93	48	M	99	3
59	5/23/97	C822	14	2/15/93	51	M	25	3
60	5/23/97	C822	14	10/27/93	43	F	601	0
61	5/23/97	C822	14	6/03/93	48	F	601	0
62	5/23/97	C822	14	11/10/93	42	F	33	3
63	5/23/97	C822	14	12/07/93	42	F	24	3
64	5/23/97	C822	14	8/25/93	45	M	54	3
65	5/28/97	C790	14	2/27/93	51	F	27	3
66	5/28/97	C790	14	5/17/93	48	M	12	3
67	5/28/97	C791	14	3/27/93	50	M	601	0
68	5/28/97	C791	14	3/23/93	50	M	37	3
69	5/28/97	C791	14	8/18/93	45	F	601	0
70	5/28/97	C791	14	4/12/93	50	F	601	0
71	5/28/97	C791	14	7/28/93	46	F	23	3
72	5/28/97	C791	14	2/27/93	51	F	601	0
73	5/30/97	C682	17	10/08/93	44	M	601	0
74	5/30/97	C682	17	11/09/93	43	M	601	0
75	5/30/97	C682	17	3/08/93	51	M	601	0
76	5/30/97	C682	17	6/08/93	48	F	601	0
77	5/30/97	C682	17	7/08/93	47	F	601	0
78	5/30/97	C682	17	4/04/93	50	F	601	0
79	5/30/97	C682	17	7/05/93	47	M	601	0
80	5/30/97	C682	17	3/25/93	50	F	601	0
81	5/30/97	C682	17	9/02/93	45	F	601	0
82	5/30/97	C682	17	11/09/93	43	M	601	0
83	5/30/97	C682	12	11/25/93	42	F	601	0
84	5/30/97	C682	12	2/25/93	51	F	601	0
85	5/30/97	C682	12	3/22/93	50	F	601	0
86	5/30/97	C682	12	10/11/93	44	F	601	0
87	5/30/97	C682	12	6/14/93	48	M	601	0
88	5/30/97	C682	12	10/22/93	43	M	601	0
89	5/30/97	C682	12	9/16/93	44	F	601	0
90	5/30/97	C682	12	4/08/93	50	F	601	0
91	6/02/97	C848	14	5/24/93	48	M	322	6
92	6/02/97	C848	14	6/25/93	47	M	601	0
93	6/02/97	C848	14	12/13/93	42	F	601	0
94	6/02/97	C848	14	9/19/93	44	F	601	0
95	6/03/97	C060	14	8/29/93	45	F	601	0
96	6/03/97	C060	14	8/23/93	45	M	601	0
97	6/03/97	C060	14	12/03/93	42	M	601	0
98	6/03/97	C060	14	3/12/93	51	F	601	0
99	6/03/97	C060	14	12/03/93	42	M	601	0
100	6/03/97	C060	14	12/09/93	42	M	601	0

Mold-Rite Plastics Inc.  
1206-006  
July 2, 1997

Test Supervisors

1	-	Shirley Kasper
2	-	Betty Rousseau
3	-	Susan Jakober
4	-	Linda Contiliano
5	-	Lissa Perritt
6	-	Scott Perritt
7	-	Richard Ward
8	-	Kelley Dippold
9	-	Anita Burgey
10	-	Elaine Villani
12	-	Paula Giannotti
14	-	Susan Davies
15	-	Marie Gerland
16	-	Helen Lambert
17	-	Joyce Osborne
19	-	Norma Swale
26	-	Carol Biddenger
27	-	Jody Kloch
28	-	Susan Pazornick

Methods of opening

0	-	Not opened
1	-	Correct method
2	-	Used fingernail
3	-	Used fingers
4	-	Used teeth
5	-	Used feet
6	-	Shelled
7	-	Damaged package
8	-	Touched indicator
9	-	Used teeth and fingers
10	-	Banged on floor
11	-	Caused noticeable leakage

Mold-Rite Plastics Inc.  
1206-006  
July 2, 1997

**Addendum**



April 4, 1988

"22mm F.G. TEST REPORT SUMMARY"

Package Tested: 22-400 F.G. - 4 IPT (48 hr. Removal Torque)

Evaluated According to: CFR Title 16, Part 1700 with additions and changes cited in the Advance Notice of Proposed Rulemaking, 48 Federal Register 2389 (January 19, 1983) -  
"Proposal to Amend the Poison Prevention Packaging Act Test Protocol"

Results Summary:

- |   |      |
|---|------|
| a. Child Resistant Effectiveness Before Demonstration | 100% |
| b. Child Resecuring Effectiveness After Demonstration | 100% |

Comments: The package tested meets the performance standards for the above cited CPSC procedures.

Sincerely,

PERRITT LABORATORIES, INC.

A handwritten signature in cursive script that reads 'Alexander M. Perritt'.

Alexander M. Perritt, Ph.D.  
President

A handwritten signature in cursive script that reads 'Richard A. Ward'.

Richard A. Ward  
Director of Consumer  
Product Testing



Report to: Sunbeam Plastics Corporation  
3245 Kansas Road  
Evansville, Indiana 47711-9611  
Date: March 24, 1988  
Samples of: 22-400 F.G. Closure  
Samples Received: February 11, 1988  
Contract No.: 1110-019  
Submitted by: Mr. Randy Bush

#### OBJECTIVE

The client submitted the above sample for a "mini-scale" study to determine if the unit should meet the Child-Resistant Effectiveness Standards of the Consumer Product Safety Commission for Poison Prevention Packaging.

#### PROCEDURE

The protocol for the evaluation of Poison Prevention Packaging (Code of Federal Regulations, Title 16, Part 1700) with additions and changes cited in the Advance Notice of Proposed Rulemaking, 48 Federal Register 2389 (January 19, 1983) - "Proposal to Amend the Poison Prevention Packaging Act Test Protocol" was used.

#### Panelists

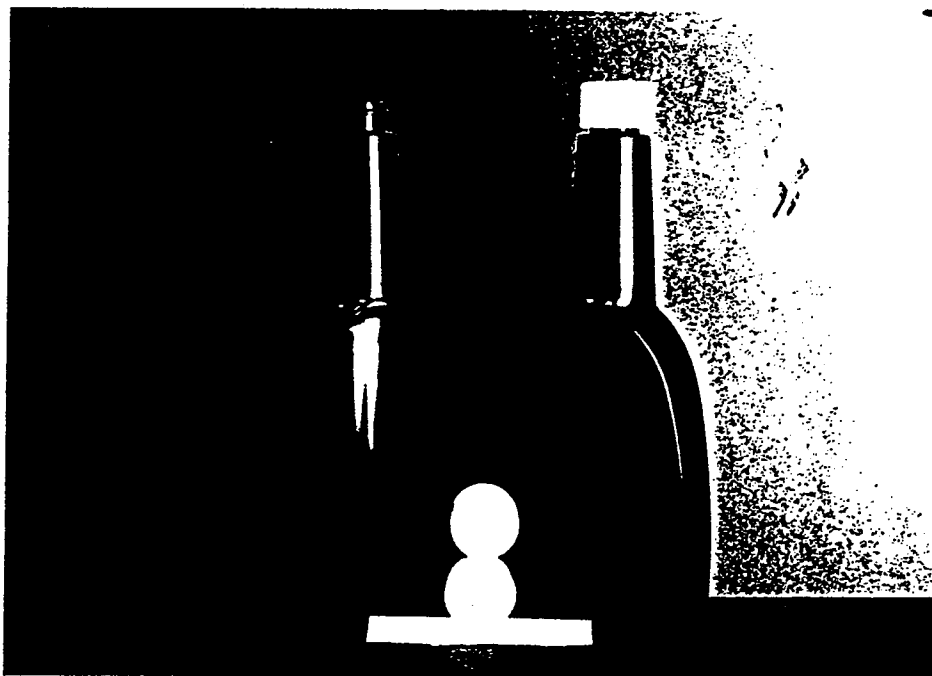
Fifty children, 42 to 51 months of age, were employed to test the unit.

No adults were employed in the study.

#### Test Unit

The test unit was the 22-400 F.G. Closure. Closures of the units were applied at 9 inch pounds of torque 48 hours prior to opening and resealing for the child test. Forty-eight plus hour removal torques averaged 4 inch pounds. Directions to open read: WHILE PUSHING DOWN TURN CLOSE TIGHTLY. A photograph appears in Figure 1 of the report. The ASTM Classification is Type I (A) Reclosable Packaging - Continuous Thread Closure, random push down while turning, no orientation of the push down force necessary.

Sunbeam Plastics Corporation  
Contract No. 1110-019  
March 24, 1988  
Page Two



22-400 F.G. Closure

Figure 1

Sunbeam Plastics Corporation  
Contract No. 1110-019  
March 24, 1988  
Page Three

### RESULTS AND DISCUSSION

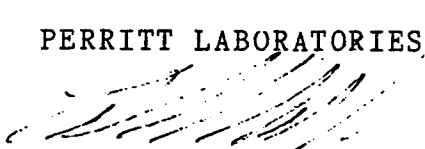
Results of the study appear in Table 1 and in the Child Test - Package Data. It will be noted in Table 1 that none out of a total of Fifty child panelists were successful in opening the unit within the ten minute test period. This represents a final unsuccessful percentage of 100.0 indicating that the 22-400 F.G. Closure meets the Protocol Standards for Child-Resistant Effectiveness.

### CONCLUSION

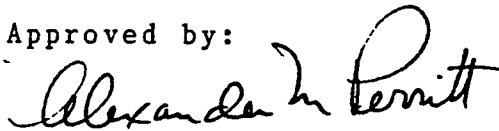
The foregoing "mini-study" employing Fifty child panelists indicates that the 22-400 F.G. Closure meets the standards for Poison Prevention Packaging Child-Resistant Effectiveness as set forth in the Code of Federal Regulations, Title 16, Part 1700 with additions and changes cited in the Advance Notice of Proposed Rulemaking, 48 Federal Register 2389 (January 19, 1983) - "Proposal to Amend the Poison Prevention Packaging Act Test Protocol".

Submitted by:

PERRITT LABORATORIES, INC.

  
Richard A. Ward  
Director of Consumer  
Product Testing

Approved by:



Alexander M. Perritt  
President

RAW:wh  
Encl.

**PL**

Sunbeam Plastics Corporation  
 Contract No. 1110-019  
 March 24, 1988  
 Page Four

Evaluation of the 22-400 F.G. Closure as a  
 Child-Resistant Package for Sunbeam Plastics Corporation

Table 1. Package opening test evaluated  
 by children 42 to 51 months of  
 age for Child-Resistant  
 Effectiveness

AGE IN MONTHS	SUCCESSFUL PANELISTS							
	PANELISTS			BEFORE DEMONSTRATION		AFTER DEMONSTRATION		TOTAL
	M	F	TOTAL	M	F	M	F	
42	2	3	5	0	0	0	0	0
43	3	3	6	0	0	0	0	0
44	2	2	4	0	0	0	0	0
45	2	2	4	0	0	0	0	0
46	3	1	4	0	0	0	0	0
47	3	3	6	0	0	0	0	0
48	2	4	6	0	0	0	0	0
49	2	1	3	0	0	0	0	0
50	3	3	6	0	0	0	0	0
51	3	3	6	0	0	0	0	0
TOTALS	25	25	50	0	0	0	0	0

UNSUCCESSFUL PERCENTAGE BEFORE - 100.00

TOTAL UNSUCCESSFUL PERCENTAGE - 100.00

PL

# **PERRITT** **LABORATORIES**

Post Office Box 147  
Hightstown, New Jersey 08520  
(609) 443-4848



August 30, 1988

## "22-400 F.G. SENIOR TEST REPORT SUMMARY"

Package Tested: 22-400 F.G. - 4.0 IPT (48 hr. Removal Torque)

Evaluated According to: CFR Title 16, Part 1700 with additions and changes cited in the Advance Notice of Proposed Rulemaking, 48 Federal Register 2389 (January 19, 1983) - "Proposal to Amend the Poison Prevention Packaging Act Test Protocol"

### Results Summary:

- |  |      |
|--|------|
| a. Senior Use Effectiveness in 5 min. test | 100% |
| b. Senior Use Effectiveness in 2 min. test | 97%  |

Comments: The package tested meets the performance standards for the above cited CPSC procedures.

Sincerely,

**PERRITT LABORATORIES, INC.**

Alexander M. Perritt, Ph.D.  
President

Richard A. Ward  
Director of Consumer  
Product Testing