LOG OF MEETING

U.S. CONSUMER PRODUCT SAFETY COMMISSION
OFFICE OF COMMISSIONER MARY SHEILA GALL

12/12/94

Commerce Procedure

SUBJECT: Child-Resistant Packaging Regulations

DATE OF MEETING: November 28, 1994

PLACE: CPSC Headquarters/Room 722

LOG ENTRY SOURCE: Bruce C. Navarro

DATE OF ENTRY: 12/6/94

COMMISSION ATTENDEES:

Commissioner Mary Sheila Gall
Bruce Navarro
Patricia Semple
Suzanne Barone

NON-COMMISSION ATTENDEES:

Ralph Engel, Chemical Specialties Manufacturers Assoc., Inc. (CSMA)
Brigid D. Klein, Attorney, CSMA
Scott A. Silvenis, Resarch Leader Packaging Innovation, DowBrands
John G. Wood, Manager, Regulatory Affairs, DowBrands

SUMMARY OF MEETING:

CSMA reiterated their comments(submitted May 20, 1994) pertaining to the inclusion of metal cans and aerosols within the scope of the protocol revision, since alternative closures do not exist at this time.

Attachment I

Founded 1914

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CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

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May 20, 1994

Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East-West Highway
Bethesda, MD 20814

RE: Requirements for the Special Packaging of Household Substances; Request for Comment on Additional Data Concerning Proposed Rule, published March 21, 1994, 59 Federal Register 13264.

Dear Madam:

The Chemical Specialties Manufacturers Association (CSMA) is a voluntary, nonprofit trade association composed of over 440 companies engaged in the manufacture, distribution and marketing of chemical specialty products such as pesticides, automotive chemicals, antimicrobial products, detergents and cleaning compounds, and waxes, polishes and floor finishes. Many of these products are subject to provisions of the Poison Prevention Packaging Act (PPPA), 15 U.S.C. § 1471 et. seq., and similar child resistant packaging requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y, and respective regulations promulgated thereunder. Accordingly, CSMA is vitally interested in changes to the Child-Resistant Packaging Regulations, particularly the child and adult testing protocols included therein.

OVERVIEW

CSMA members are committed to the implementation of improved child-resistant packaging whenever it is technically feasible, practicable and appropriate. While we support many of the changes to the proposed protocol, we have serious reservations with some of the proposed amendments, in particular the **implementation of the Senior Adult Test Panel at this**

time. Inclusion of senior adults in the testing protocol for chemical specialty products will result in elimination of many products from the marketplace.

On May 5, 1994 several CSMA members met with Ms. Suzanne Barone, Mr. Chuck Wilbur and other CPSC staff to discuss the proposed changes to the testing protocol under the PPPA. We discussed the nature of chemical specialty products and the engineering principles associated with packaging for our industry. In this submission, our comments focus on the following six issues: **1) addition of the Senior Adult Testing Panel, 2) effective date, 3) senior adult testing procedures, 4) child testing protocol, and 5) CSMA Freedom of Information Act request to the CPSC.**

I. SENIOR ADULT PANEL

The Commission is proposing to substitute a Senior Adult Test Panel, ages 60-75 for the current adult panel of 18-45 year-olds. The senior panel is to be divided into three groups, with 30% 60-65, 30% 65-70 and 40% 71-75.

A. Establishment of Standards

In developing standards for special packaging, the Commission is required to consider the following factors:

1. The reasonableness of such standard;

2. Available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness and injury caused by household substances;

3. The manufacturing practices of industries affected by the act; and

4. The nature and use of the household substances. 15 U.S.C. 1472.

The Commission has not fully or appropriately considered these mandated elements in proposing the addition of the Senior Adult Test Panel to the testing protocol for all products regulated under the PPPA.

The Commission is proposing to include the senior adult test panel because "some persons, especially older persons, find certain types of child-resistant packaging difficult to open and properly resecure." 55 Federal Register 40856. Therefore, the Commission asserts

that "a number of people either purposely purchase products in packages that are not child-resistant [which is authorized under the PPPA] or do not properly resecure the package after opening it initially." 55 Federal Register 40856. As evidence of this assertion, the Commission points to the 1989 NEISS data indicating older adults have ". . .difficulty opening or closing child-resistant medicine containers." 55 Federal Register 40861. This study details injuries to children in the pharmaceutical category. 55 Federal Register 40861. **The Commission has inappropriately generalized this data to extend to all regulated household products within its jurisdiction, including chemical specialty products.**

According to Commission staff, **CPSC does not have any data specific to the chemical specialty industry showing that consumers do not properly resecure such products after use.** The American Association of Poison Control Centers data analyzed by CPSC and utilized as a basis for the protocol change does not support the conclusion that chemical specialty products are a major source of ". . . serious personal injury or serious illness resulting from handling, using, or ingesting such substance. . ." 16 CFR § 1700.3(a)(2).

The chemical specialty industry has specific packaging manufacturing requirements because of the nature of our products. **Packaging components and materials which will survive long-term storage, transportation movement and jostling, and use-conditions must be selected.** Packaging material able to withstand the chemical components of the product must be chosen to prevent the chemical from damaging the container or causing a loosening of seams and seals. The construction materials are quite limited due to compatibility issues arising in many cases from use of some solvents, restricting the design options for a senior adult friendly child-resistant closure. When plastics can be used, containers are molded in the sizes required for the chemical specialty product, the orifice, and therefore its closure, are dictated by the size of the container. A large container cannot have a very small closure because the manufacturing process for the container prevents it. Furthermore, the larger orifice is necessary to accommodate the mechanism which fills the bottle on the packaging line.

Additionally, **the torque-dependent continuous threaded closures on packages represent a unique manufacturing challenge for the chemical specialties industry.** It is extremely important that chemical specialty containers do not leak, therefore appropriate torque to prevent leakage must be used. For some chemical specialties products, this requires closure torque of 20-30-inch pounds; a torque which is significantly higher than that used for other products such as pharmaceuticals and which surely plays an important role in ones ability to open the container.

Although the CPSC staff has indicated that 80% of the closures used for pharmaceutical products can also be used for chemical specialty products, this is a misconception. The packaging needs of these two industries are quite divergent. Unlike medicines, the seal for a chemical liquid container must be more stringent than the seal for a "dry" medical tablet or a cough medicine where minimal container leakage does not pose a hazard to a child. In addition, unlike medicines, the packages for chemical specialty products

are usually much larger in size and different in shape to accommodate special application purposes which vary widely. CPSC has not properly considered these issues.

As detailed in our July 1, 1991 comments to CPSC concerning an earlier proposal, there are also numerous differences in the use patterns between medicines and chemical specialty products:

1. Unlike medicines, the failure to gain immediate access to chemical specialties will not have an effect on health preservation or restoration;

2. Unlike medicines, chemical specialties do not generally have to be opened daily or multiple times in a day; and

3. Unlike medicines, some of the use patterns which lead to exposure such as leaving medicines out in the open so that seniors are reminded to take the medicine on the assigned schedule, or carrying the medicines in a non-child-resistant package in a packet or purse do not occur with other regulated products. Thus, these products are more likely to be kept out of the reach of children in a senior adult household even if the package is rendered non-child-resistant.

With respect to the proposed addition of the Senior Adult Test Panel, the CPSC should regulate the pharmaceutical industry separately from the chemical specialty industry. There are substantial differences in use patterns, and storage practices as well as packaging requirements, which justify such a regulatory approach.

B. Technical Feasibility, Practicability and Appropriateness of Senior Adult Test Panel

Section 3(a)(2) of the PPPA, 15 U.S.C. § 1472(a)(2), requires that the standard imposed for special packaging be "technically feasible, practicable and appropriate."[1] In

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[1] "Technically feasible" means that package designs that would meet the requirements of 16 CFR 1700.15(b), and that would be suitable for use with the products subject to the rule, are or can be available. A standard is "practicable" when special packaging for the products covered by the rule is adaptable to modern mass production and assembly line techniques. That special packaging is "appropriate" is established by showing that special packaging can be available in forms that are not detrimental to the integrity of the substance and do not interfere with its storage or use. 55 Federal Register 40658 citing S. Rep. No. 91-345, 91st Cong. 2d Sess. 10 (1970).

order to fulfill this statutory mandate, CPSC conducted tests on closures during the summer of 1993. The results of these studies were set forth in a report dated September 1993.

The 1993 PPPA Senior Adult Use Effectiveness Protocol Tests included ten packages. Only four of the packages were reclosable: 1) a 28 mm continuous threaded cap with liner and tamper resistant shrink neck band on a white round plastic 50 tablet bottle, 2) a 35 mm continuous threaded cap without a liner on a 50 ounce handled bottle with two locking notches, 3) a 35 mm lug cap on a prescription vial, and 4) a 33 mm snap cap on a white round plastic bottle. This narrow range of testing included two closures which are not generally utilized for chemical specialty products (i.e., lug cap and snap cap). In addition, the 28 mm cap was tested on a package too small (50 tablet bottle) to provide any useful data for our industry because size, shape and torque are key factors in whether a package passes senior testing under the proposal.

None of the non-reclosable packages tested are suitable for use by the chemical specialty industry and no aerosol packages were tested. Therefore, we do not agree with the CPSC staff's conclusion that "the results provide evidence that senior-effective packaging can be developed (technically feasible), can be mass produced (practicable), and can provide adequate packaging for the range of PPPA-regulated products (appropriate)." 59 Federal Register 13266.

The only closure used in the above mentioned testing which is representative of closure used on a chemical specialty product was the 35 mm continuous threaded cap on a 50 ounce bottle. CPSC staff has stated that since this closure passed the Senior Adult Test Panel at 90%, it demonstrates than an acceptable closure is available for broad use by the chemical specialty industry and that the Commission has met the statutory burden of only requiring special packaging that is "technically feasible, practicable and appropriate" for a substance. CSMA takes strong exception to this conclusion and submits that the proported existence of one closure does not fulfill Congress's statutory intent that special packaging be technically feasible, practicable and appropriate. The staff's conclusion is error not only because it does not reflect the clear intent of the PPPA, but also for other reasons.

In issuing previous standards for special packaging, the Commission has found that the requirement of technical feasibility is satisfied by information indicating that there are "...numerous forms of special packaging available." 44 Federal Register 51212 (Emphasis added). With the current proposal, the Commission is relying on the test results of a single closure as proof of technical feasibility, practicability and appropriateness for an entire industry, without taking into consideration, among other things, the specific packaging needs of the industry, the sizes of packages needed, the chemistry of the products to be regulated, and the physical characteristics of the package necessary to maintain the integrity of the

product/package (such as torque). These factors must be considered and satisfied as a requisite to the conclusion that packaging is technically feasible, practicable and appropriate.

Even setting aside the statutory mandate and Congressional intent, the CPSC staff's assertion that there is an acceptable child-resistant closure available for broad industry use is mistaken. The very closure/container system depended on by CPSC and used on the product in the recent testing (35 mm continuous threaded cap on a 50 ounce bottle) is not readily available to the chemical specialty market. The specific molds to the 35 mm cap and the 50 ounce bottle tested are owned by the company marketing the consumer product not by the closure manufacturer. And while the closure cap supplier indicates that the technology exists to make a similar cap for someone else, this is a six to nine month process, and this timeframe does not include multiple redesign and retest to insure efficacy, each taking several months, or protocol testing. Moreover, such an effort may involve an expenditure of up to $400,000. Each container and cap combination must be evaluated to determine effectiveness because a cap that successfully passes the child-resistant protocol on one package design may not work on another. The Commission recognized these variables when it ". . .advised that changing the size of a design often reduces the child-resistant effectiveness." 44 Federal Register 13020.

Even if a closure, such as the tested 35 mm continuous threaded cap, can be successfully produced to fit a wide variety of containers, it is not appropriate for every type of chemical specialty product. The package design and materials must be compatible with the product and allow for safe shipping, use and storage and thus a plastic closure of this type would not be appropriate for an aerosol product or for an aggressive liquid which will attack plastic, and therefore must be packaged with metal. In short, it takes a comprehensive effort to develop and produce a closure/container package system, no single system is suitable for our industry.

1. Child-Resistant Aerosol Overcap

Aerosol child-resistancy and adult use effectiveness are currently achieved through the use of "squeeze and pull" aerosol overcap, see pictures 1 and 2. Child-resistancy is accomplished by arching retention beads positioned on the inner shell of the overcap, see picture 3. The retention beads are positioned on the inner shell of the overcap, see picture 4. The retention beads are positioned approximately 90 degrees from the consumer depression region on the closure's exterior. The retention bead profile, see pictures 5 and 6, and dimensional tolerances are critical to the overcap's child-resistance ability.

The variability in can dimensions, valve cup dimensions, valve crimping process, see pictures 7, 8, 9, 10, and 11, and plastic overcap dimensions produces a narrow window for proper child-resistance functionality. In the current design, a reduction in the retention beads would make the overcap easier to remove for seniors, thus increasing adult use effectiveness,

but would compromise the child-resistance of the package (since children commonly bang the package on the floor).

To meet the new standard, a completely new aerosol packaging system would need to be developed to address senior consumer package access while accommodating package design limitations and manufacturing variability. Berry Plastics, a major supplier of CR aerosol overcaps, estimates a developmental and commercialization timetable of 24 months for a child-resistant aerosol overcap which addresses the above design constraints, see Attachment I. Of course, there is no guarantee that this closure will in fact pass the Senior Adult Test Panel.

An overcap system which utilizes a tool to remove the overcap is not recommended for a pressurized container containing caustic material. Should the consumer inadvertently misuse the tool, the tool could puncture the dome of the aerosol package. Pressurized caustic material, which may result in severe chemical burns to skin and eyes, would then be sprayed uncontrollably onto the consumer and into the room. From a product stewardship position, use of a tool to open an aerosol package of this type cannot be implemented. In addition, misuse of an opening tool could compromise the child-resistant features of the overcap. Once the overcap has been damaged, the package is no longer child-resistant.

2. Metal Cans

High solvent products such as paint and varnish removing products, specialty wood cleaning, coating and finishing products, and floor waxes and polishes are packaged for consumer use in metal containers, see pictures 12 and 13. The use of metal containers is driven by product compatibility and flammability. Some products require metal-shelled child-resistant closures, see pictures 14 and 15, since chemicals in the product will react with plastic closures and liners, thereby reducing the integrity of the child resistant closure. Some products even require a metal plug for shipping and distribution. If a metal plug is used with a plastic child-resistant closure, the closure would begin to degrade once the consumer removed the shipping plug. The reaction of the product with the plastic caps would cause swelling and stress cracking, thus compromising the child-resistance of the package. In addition, these products require very high torques, i.e., 20-30 inch-pounds, to insure positive seal given the volatile solvents and metal neck-finish which mates with a metal closure rather than a softer plastic material.

To date, no alternative for these caps exists and the major supplier of the closures, Sunbeam, estimates that it will take up to 24 months to commercialize a suitable replacement, provided design and compatibility issues are fully resolved, see Attachment II. Again there is no guarantee these closures will pass the proposed Senior Adult Test Panel. These factors should be considered by CPSC before including all products to use the revised protocol with the Senior Adult Test Panel.

C. Industry Testing

The chemical specialty industry has good reason to be concerned about the implementation of the senior adult protocol as it applies to chemical specialties products. In 1991, a group of CSMA companies tested twelve of their products using the Senior Adult Test Panel protocol proposed by CPSC on October 5, 1990 (using the 5 minute/1 minute test), see, Attachment III. Ten of the twelve closures failed to meet a 90% pass rate. The two closures that passed did so only marginally at 90 and 92%, and it is unlikely that these results are reproducible since they passed at less than the necessary plus or minus 3%.

CPSC staff has been critical of this testing because it included only 50 senior adults, however, the test failures are low enough to safely conclude that even if the full 400 adults permitted under the sequential test method were used, that the closures would still fail. Although the current protocol proposal has changed from that proposed in 1990, the chemical specialty industry believes that our products will still fail.

The requirements under the proposal are not technically feasible, practicable or appropriate for the chemical specialty industry at this time. If the revised protocol is adopted as proposed, it will result in the unnecessary and improper elimination of many important consumer products. The Commission should not implement the Senior Adult Test Panel provisions for chemical specialties products at this time.

II. EFFECTIVE DATE OF SENIOR ADULT TEST PANEL PROVISION

A one year effective date for implementation of the Senior Adult Test Panel provision is unreasonable for the chemical specialty industry. Even if appropriate closure/container systems were available, the one year effective date will not provide sufficient time for companies to convert all their products regulated under the PPPA to new closures and packages which will pass the revised protocol. CSMA realizes that the Commission is limited by the requirements of the PPPA, which specify that ". . .the effective date shall not be sooner than 180 days or later than 1 year from the date the standard is promulgated. . ." 15 U.S.C. 1471(n).

The Commission should understand that there are a number of things that must occur within the one year effective date. Once the protocol is finalized, all closure/container systems currently utilized will need to be tested to determine compliance. Although the Commission staff states that such testing can be started at this point, we do not agree since the protocol is in a state of flux. Two significant changes were made to the 1990 proposal based on comments received: 1) dividing the senior panel into three age groups with 30% 60-64, 30% 65-70, and 40% 71-75, and 2) use of sequential testing. The current proposal is still open to comment and since the Commission is required by the Administrative Procedure Act, 5 U.S.C. § 553(c), to consider ". . . relevant matter presented. . .," the protocol is subject to further revisions. It is unrealistic to expect industry to devote significant resources to

testing without having a finalized protocol. One company estimates that it will cost $100,000-200,000 just to determine the status of their products under the new protocol; these figures do not, of course, reflect the cost of full compliance.

Closures that do not pass will need to be redesigned. Attachment IV is a timeline which overviews the steps that must be taken in the development of a new package. **Assuming that there are no failures along the way, it takes approximately thirty-seven months to develop and bring a new child-resistant closure to market.**

Since there are only six testing labs equipped to complete the necessary testing (one of which has never carried out senior adult testing), there will be a large backlog of testing requests after the effective date of the rule, see Attachment V. The testing labs have indicated that it will be difficult to obtain the participation of the 400 adults needed for the sequential testing, especially in the 60-64-year-old age bracket, which will further delay the testing.

Companies will need several years to completely convert to the proposed requirements, based on the number of packages to convert, testing lab availability and time required to develop and test new molds for closures and bottles. In order to assist in the conversion process, CSMA suggests that the Commission appoint a Voluntary Advisory Task Force for chemical specialty products. **The task force, comprised of CPSC staff, industry, closure suppliers, testing labs, and standard setting bodies, should serve as an information resource to distribute information on new packaging technology which is being developed.** Of course, the competitive nature of industry must be recognized, not all suppliers will want to be forthcoming with specific details, but any information flow will certainly help to speed the conversion process.

The task force could also **provide assistance to small businesses which will likely experience difficulty complying with the protocol changes.** Small businesses probably will not have sufficient volume to command the attention of closure suppliers and testing labs, and will, therefore, require extra help in compliance.

The Commission staff has taken the position that implementation of a Senior Adult Test Panel will spur on the industry and/or closure manufacturers to develop closures meeting the senior adult use effectiveness. While such a theory might appear to be reasonable, in essence it is not. As mentioned before, there are several difficulties in developing new closures; it is a major undertaking which can require years to complete. In our economy the incentive to develop a closure must be fostered by a realistic assessment of market demand to cover development costs and make a profit. Absent such incentives, no amount of governmental pressure will be able to overcome what would be an unwise business decision. **Realistic cost, timing, and benefits need to be factored into the implementation timeframe.**

Therefore, **we suggest phasing-in the Senior Adult Testing Panel provision by virtue of future rulemaking as closure/container systems become technically feasible, practicable and**

appropriate for the chemical specialty industry. This could be accomplished under Section 8 of the PPPA in a simple and timely fashion since the Section provides that the Secretary for good cause shown can determine, ". . .an effective date is in the public interest and publishes in the Federal Register his reason for such finding, in which case such earlier date shall apply."

CSMA believes that this approach would foster a smooth transition for implementation of the Senior Adult Testing Panel provisions for the chemical specialty industry. First, the Senior Adult Testing Panel protocol would be firmly in place and would not change. Thus, the closure and chemical specialty industry could develop packaging based on the final protocol. Second, by virtue of the task force, industry, the Commission and interested parties can be working together to provide an information exchange and thus encourage communication between the closure manufacturers and the user industry. Third, from the Commission's viewpoint, it would not require an inordinate amount of work to complete the future rule making process, since the protocol would already be in effect for a portion of products and the phase-in of the chemical specialty industry would merely necessitate a finding by the Commission based on facts from the task force and other Commission sources that needed packages are now technically feasible, practicable and appropriate. Staff could transmit this information to the Commission by virtue of a briefing package for Commission action. Finally, if the Commission chooses to do so and compliance can be achieved, by virtue of Section 8 of the PPPA, a shorter effective date could be promulgated.

This process involves all parties in an open and coordinated effort to achieve a common goal, while permitting needed and valuable consumer products to remain on the market, and allowing for an appropriate phase-in of chemical specialty products. Accordingly, we urge the Commission to take this approach, and CSMA would be a willing participant on the task force.

III. SENIOR ADULT TESTING PROCEDURES

CSMA does not believe that the proposal to include a Senior Adult Test Panel has been supported in accordance with the PPPA for the chemical specialties industry. However, we offer the following comments regarding testing using the proposed Senior Adult Testing Panel.

A. Panel Participant Selection

Section 1700.20(a)(3)(i) should allow for 25% of the senior adults to be obtained from a test site, not the proposed 24%. This will allow for the use of four test sites, instead of five.

B. Sequential Testing

We recommend the ability to use the full 400 adults or the sequential test method under section 1700.20(a)(3)(ii) for maximum flexibility.

C. Test Instructions for Senior Adults

Under Section 1700.20(a)(3)(iii), in order to be consistent and clear in the instructions which the test facilitator gives to the test subjects, the facilitator should always state, "Please close this package properly." This makes it clear to the test subject that it is important and necessary to both open and properly close the package. The screening test requires this language. In the actual test, if the current instruction, "please close," is used, the subject may think that the test is merely to open the package and not to properly open and resecure the package.

In addition, the directions for use on the test container should be of approximately the same type size and font as would be found on a package commercially available to consumers.

D. Screening Test

The proposed screening test for senior adults, intended to screen out those who may not have the mental or physical abilities to open and properly resecure any threaded closure packaging, whether child-resistant or non-child-resistant, is biased against household chemical specialties products that require or use continuous threaded child-resistant packaging.

The proposal specifies that a non-child-resistant continuous threaded 28 mm cap with a liner was used for the screen test, with the closure resecured to 10 inch-pounds of torque at least 72 hours before testing. This is by no means representative of the chemical specialty product, which would typically require 12-30 inch-pounds of torque in securing a closure of this size.

The torque will stabilize after about 72 hours at a removal torque that is about 1/2 to 2/3 the application torque. Therefore, the removal torque of the non-child-resistant package would be down to 5-7 inch-pounds at the time of the test. These values are at the lower end of the removal torque range one would expect for continuous threaded closures being tested on the child-resistant test packages. In the above illustration, a senior who has already demonstrated a problem opening or properly closing the child-resistant package during the 5 minute package familiarization test period, may in fact be able to open the low torque non-child-resistant test package, but then fail the subsequent final one minute child-resistant tests because the torques being tested are nearly always higher (as much as 40%) than for the non-

child-resistant package. **This test method is therefore biased towards passage of the screening test, and failure of the senior-adult child-resistant package test.**

Gerontologists and professionals involved in biomechanics, industrial design, and human factors design, indicate that the weight and shape of the package and the diameter of the closure will impact the ability to remove the closure. A child-resistant closure requiring two dissimilar motions to remove applied at production application torque to a 32 oz package (applied at over 25 inch pounds) may not be able to be opened by certain senior adults. Because the same adult passes the CPSC screening test in no way indicates that they could open any child-resistant package.

If the goal of the CPSC is to foster the development of senior friendly package systems, then the method by which the closures are evaluated should be reproducible and provide "equal treatment" for all packages being evaluated. Since there is variability in the senior population (with the level of activity being a key determinant in the loss of muscle strength), the screening test should be the use of a child-resistant closure which has passed the proposed protocol and is of similar size and weight as the test package. Only by using this "Gold Standard" closure can we be certain that the test subject can indeed be a valid test subject.

IV. CHILD TEST PROTOCOLS

A. Standardized Child Test Instructions

The language of the child test protocols differs from that of the senior adult test protocols in that packages are to be resecured 72 hours before testing, implying that the closure has been secured at least twice before the test is administered. No torque requirements are mentioned, therefore, this could lead to undo influence, conscious or unconscious, on the pass/fail results of the child test.

There is no problem with the number of times the package is opened before children test its effectiveness, but care needs to be taken to always replace the closure within production application torque tolerances and the tester that opens the package before the children's test should reapply with torques slightly higher than typical 72 hour removal torques.

B. Sequential Testing

Section 1700.20(a)(2)(iii) should permit the use of the full 200 children or the sequential test method to allow for flexibility.

C. Adult-resecuring test

The need for the adult-resecuring test needs to be clarified. It appears that the decision to do the test may be based on the subjective opinion of the testing lab, i.e., can the closure be determined to be closed visually. Visual observation, without further guidance is too subjective. More guidance is needed on the decision to complete the resecuring test.

D. Reduction in Child-resistance

Many consumer product packages are capped with expectionally high torque in order to prevent leakage during shipping and distribution. Many of these products contain solvents or other materials which could damage surfaces if bottles leaked improperly, so high torquing is necessary. The child-resistant closure systems used on such chemicals have been very effective at preventing childhood ingestions. The chemical specialty industry listens closely to consumers and uses feedback received to modify products and packages. Inability to access or reclose our products by seniors has not been an area of widespread consumer calls or complaints. When such calls or complaints have been received, package modifications have been made, where possible.

If industry is forced to use a closure system design which allows for easier senior access to the product, the CPSC may have to accept a lower level of child-resistancy on these products than what is achieved with the current child-resistant designs in use. In some cases, that might mean a sizable reduction in child-resistancy for a given class of products.

V. FREEDOM OF INFORMATION ACT REQUEST

On April 1, 1994 CSMA filed an information request pursuant to the Freedom of Information Act, 5 U.S.C. § 552. While staff has provided us some information, we are still waiting for a formal response from the CPSC and reserve the right to submit further comments to the Commission based the issues raised by the information we receive.

dated May 20th

CONCLUSION

CSMA members realize the necessity and importance of the use of child-resistant closures in the prevention of accidental ingestions and have been supportive of their use. We are willing to work to ensure that closure/container systems are both child-resistant and senior friendly. However, at this time, the proposed senior adult protocol is not technically feasible, practical or appropriate with respect to the chemical specialty industry.

We believe that our suggestion with respect to temporarily excluding the chemical specialty industry from the Senior Adult Testing Panel provisions, with eventual phase-in

coupled with our suggested Voluntary Advisory Task Force, is an appropriate manner to move this process to fruition. We further believe such an approach would be fair and would represent a unique opportunity to put a program in place involving all affected parties in order to achieve senior friendly child-resistant packaging.

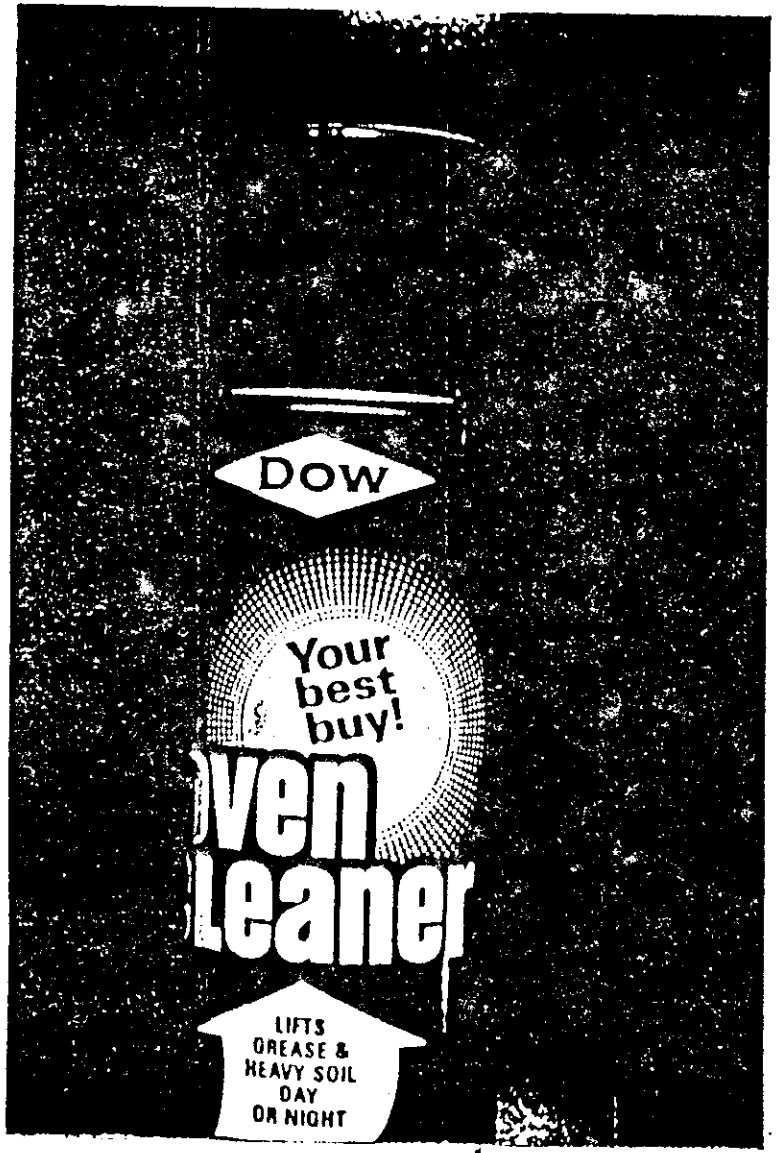
We appreciate consideration of our comments and look forward to continuing to work with the Commission on this issue.

Sincerely,

Stephen S. Kellner
Vice President
Legal Affairs

Attachments

PICTURE 1



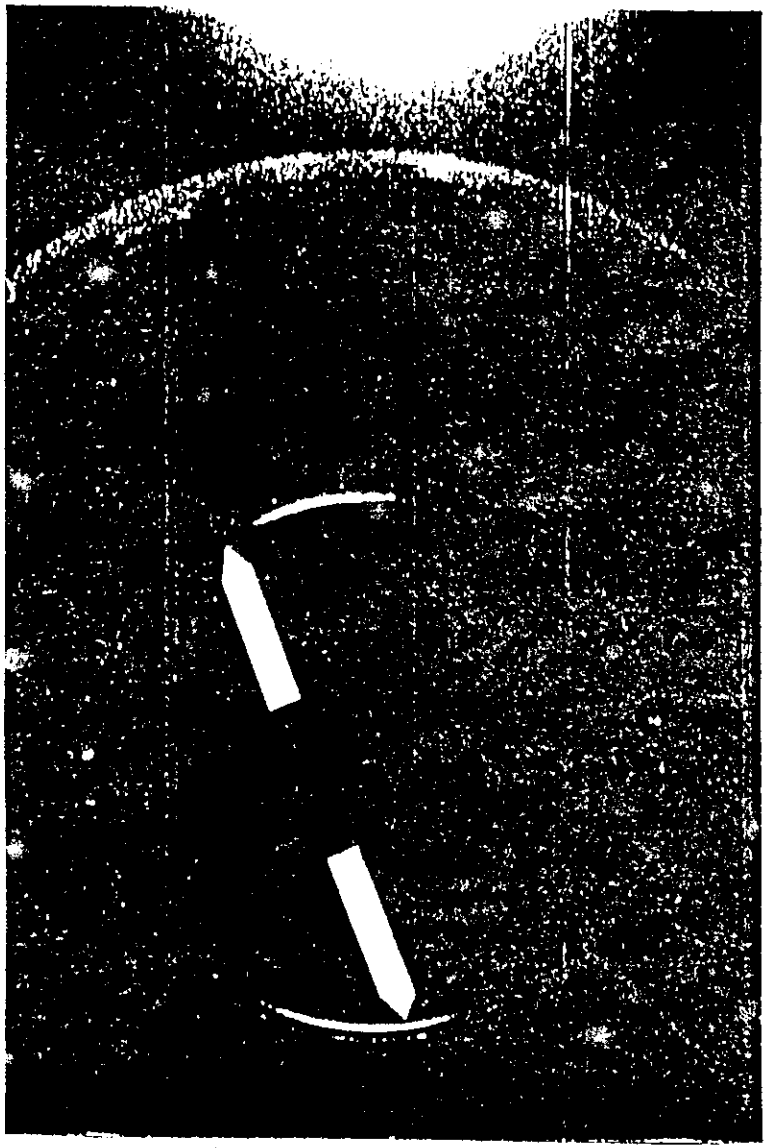
DOW OVEN CLEANER* Aerosol Package. Product sold by DowBrands, L.P..

*Trademark of The Dow Chemical Company

PICTURE 2

DOW OVEN CLEANER* Aerosol Package with the overcap removed.

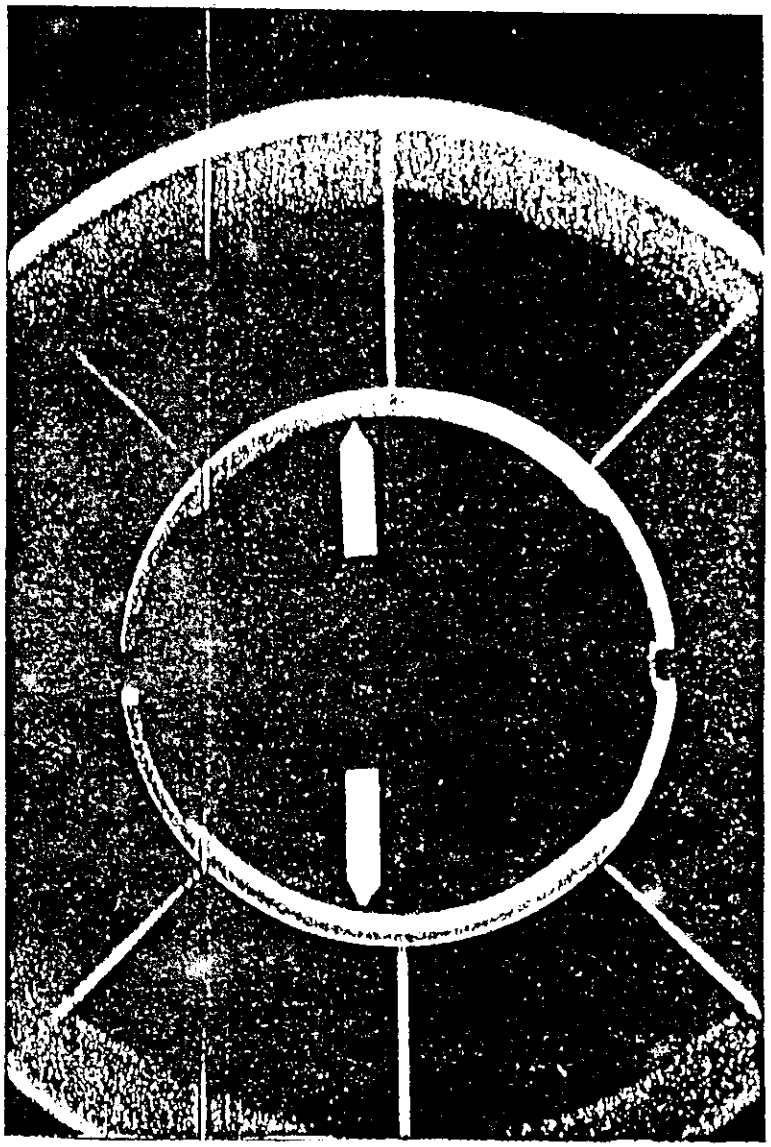
PICTURE 3



Bottom close-up view of child-resistant aerosol used on Aerosol DOW OVEN CLEANER*. Arrows depict retention beads.

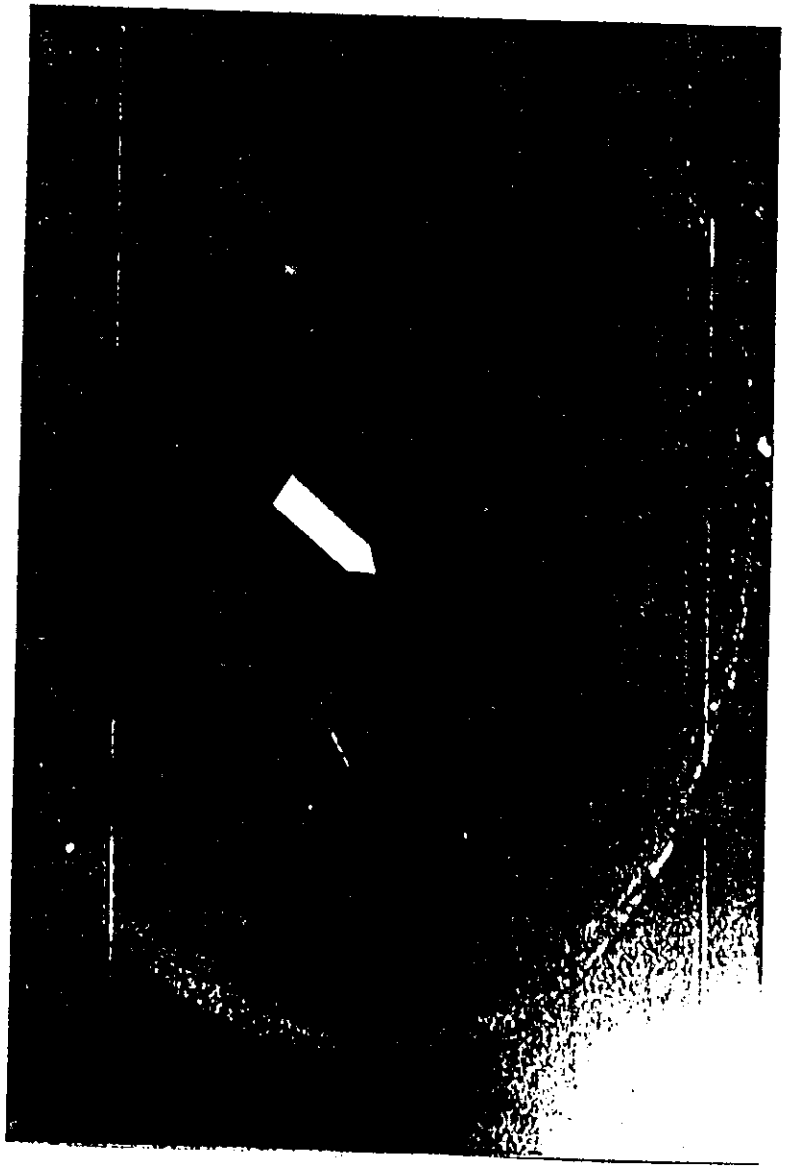
*Trademark of The Dow Chemical Company

PICTURE 4



Bottom close-up view of child-resistant aerosol used on EASY-OFF® HEAVY DUTY CLEANER. Arrows depict retention beads.

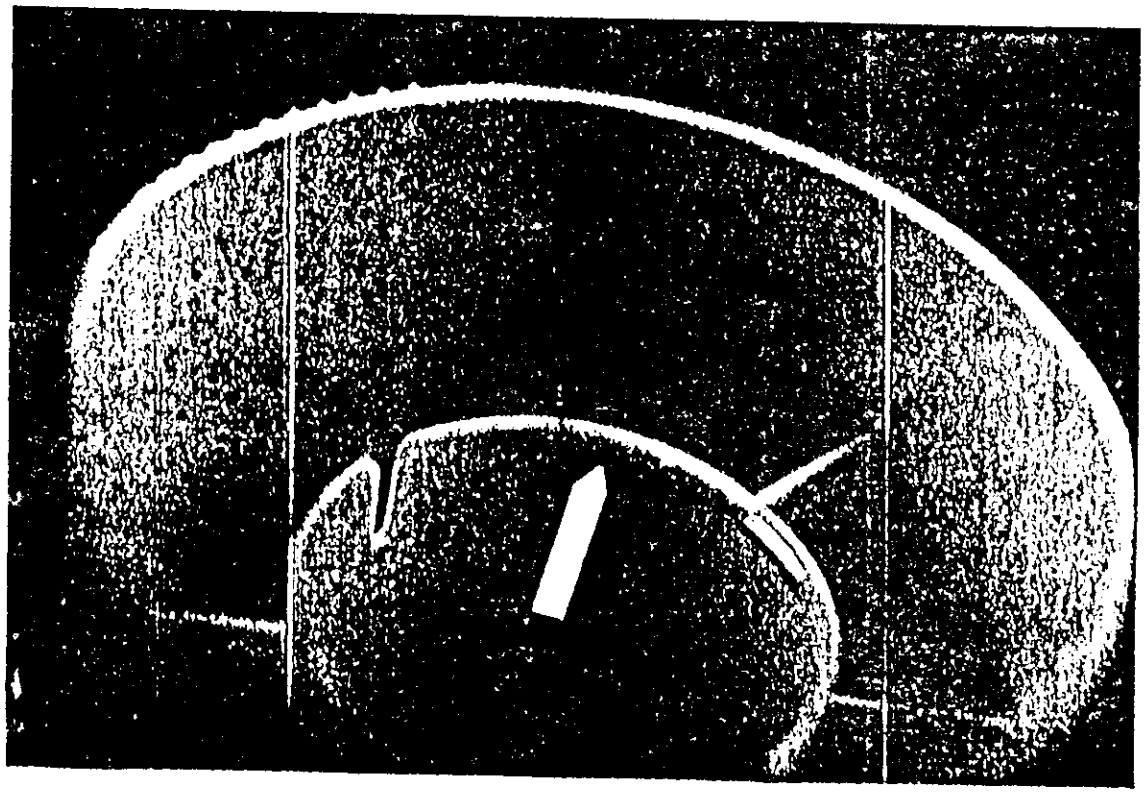
PICTURE 5



Angled close-up view of child-resistant aerosol overcap used on DOW OVEN CLEANER*. Arrow depicts retention bead profile.

*Trademark of The Dow Chemical Company

PICTURE 6



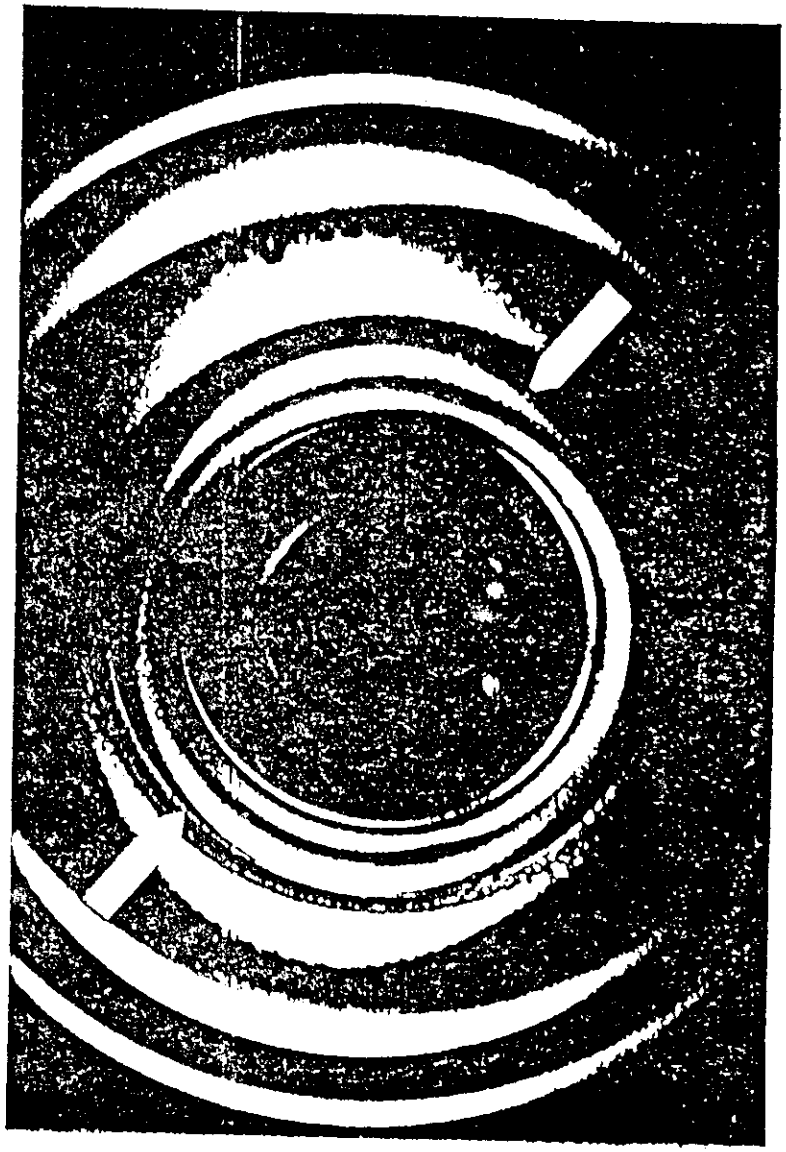
Angled close-up view of child-resistant aerosol overcap used on EASY-OFF® HEAVY DUTY OVEN CLEANER. Arrow depicts retention bead profile.

PICTURE 7

Close-up Side View of DOW OVEN CLEANER* Aerosol Package. Arrow point to crimped valve cup. The retention bead of the aerosol overcap seats in the small space underneath the crimped valve.

*Trademark of The Dow Chemical Company

PICTURE 8

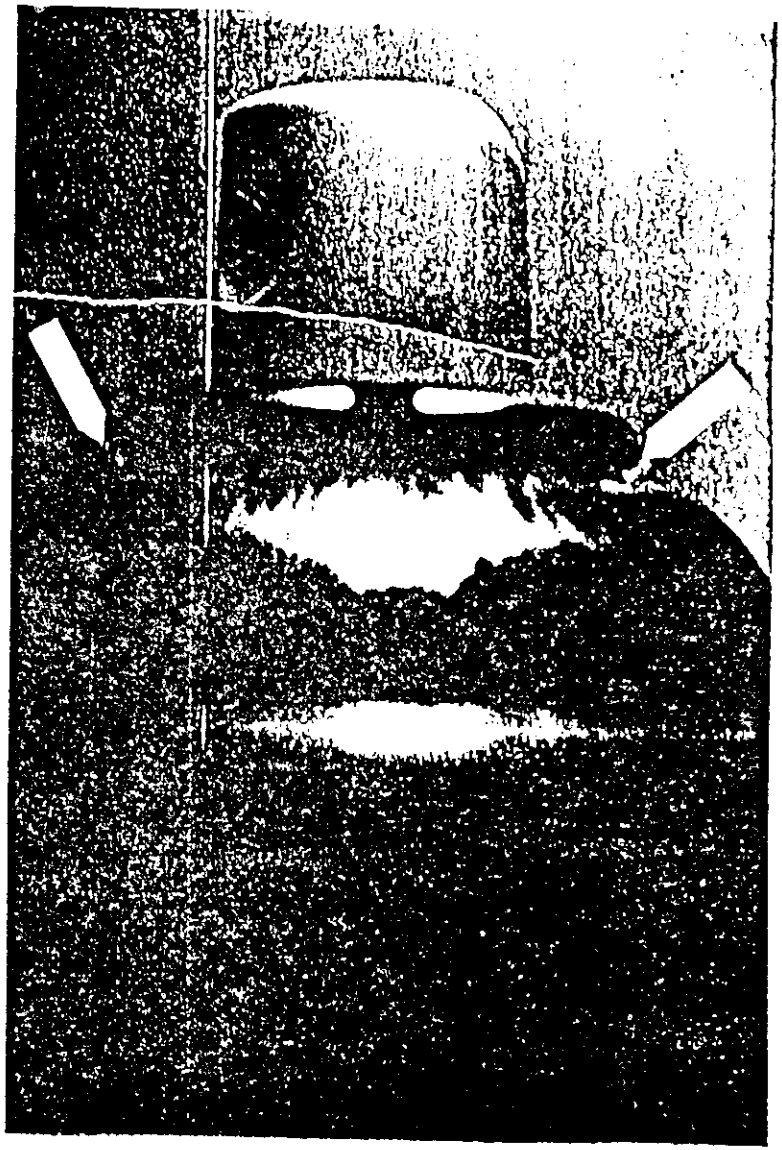


Close-up Top View of DOW OVEN CLEANER* Aerosol Package. Arrows point at diameter of crimped valve cup.

PICTURE 9

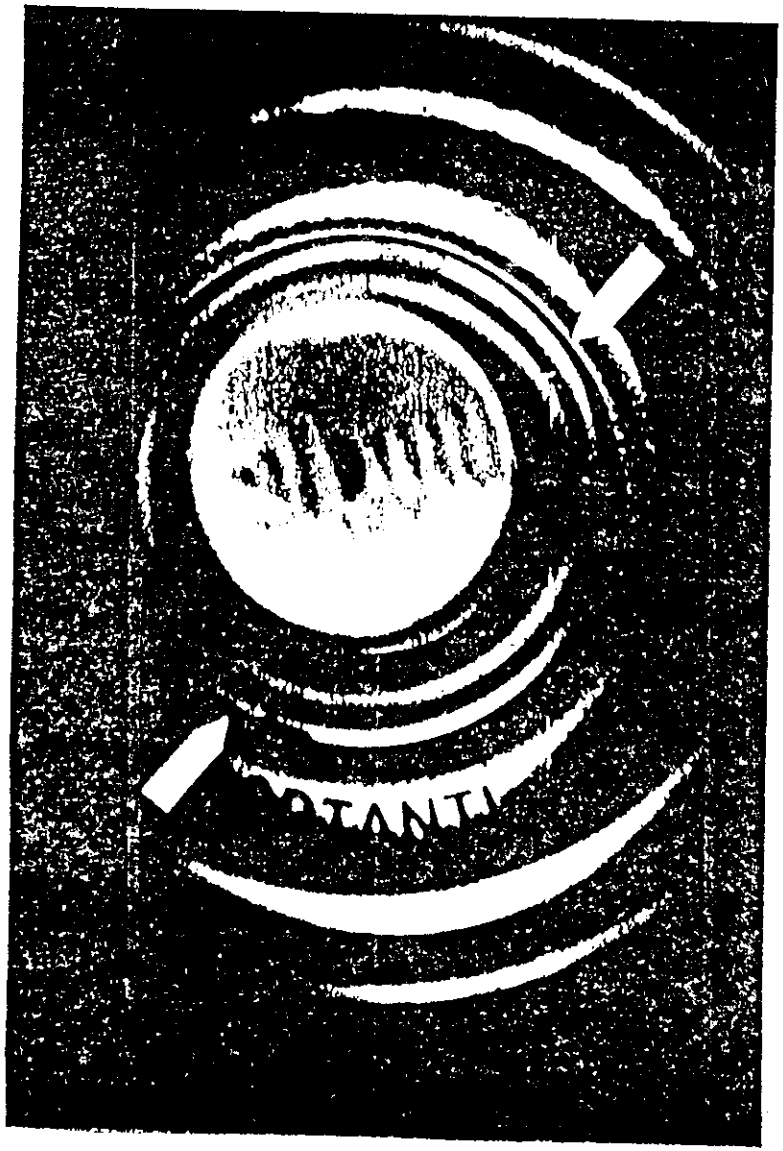
EASY-OFF® HEAVY DUTY OVEN CLEANER. Product sold by Reckitt & Coleman, Inc..

PICTURE 10



Close up side view of EASY OFF® HEAVY DUTY OVEN CLEANER. Arrows point to crimped valve cup. The retention bead of the aerosol overcap seats in the small space underneath the crimped valve.

PICTURE 11

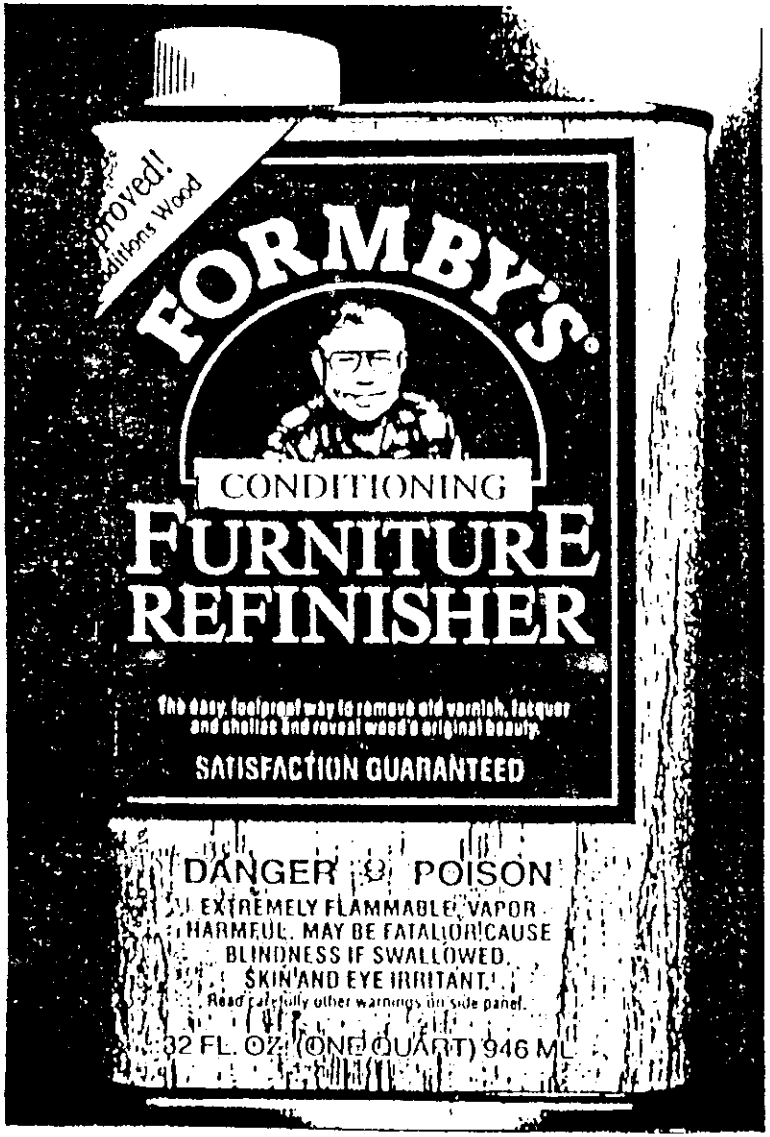


Close-up Side View of EASY OFF® HEAVY DUTY OVEN CLEANER. Arrows point at diameter of crimped valved cup.

PICTURE 12

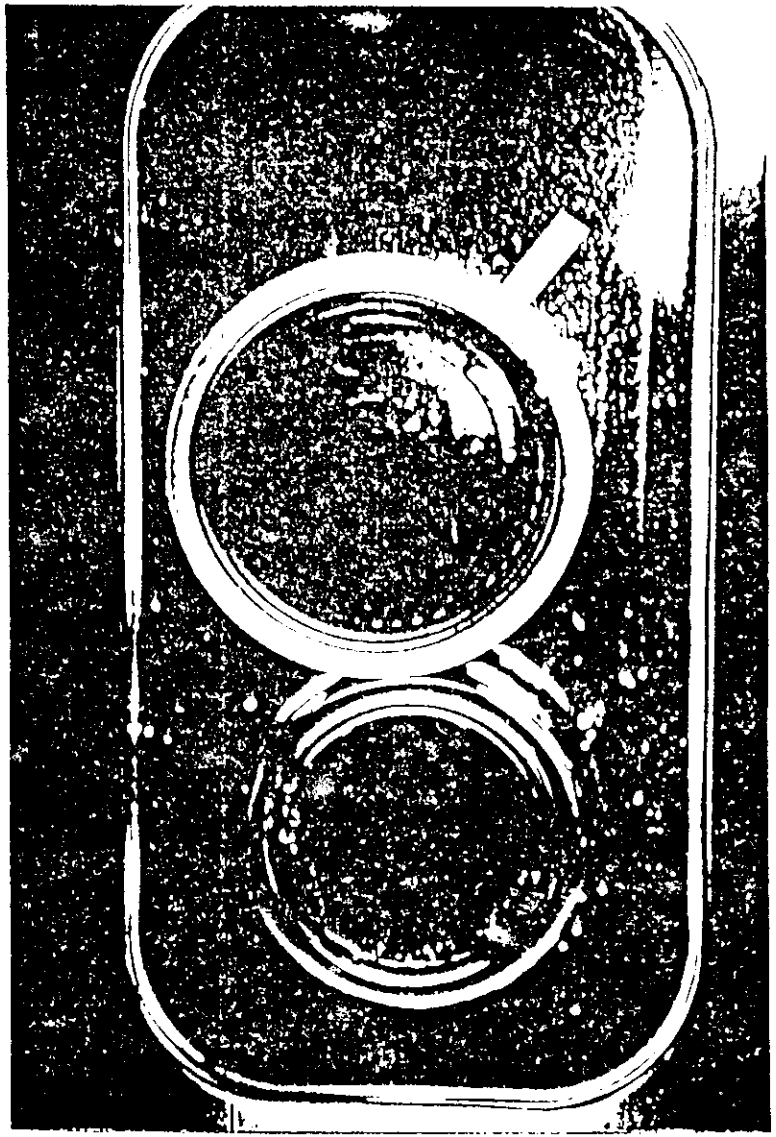
RED DEVIL® PAINT AND VARNISH REMOVER. Product sold by L&F Products.

PICTURE 13



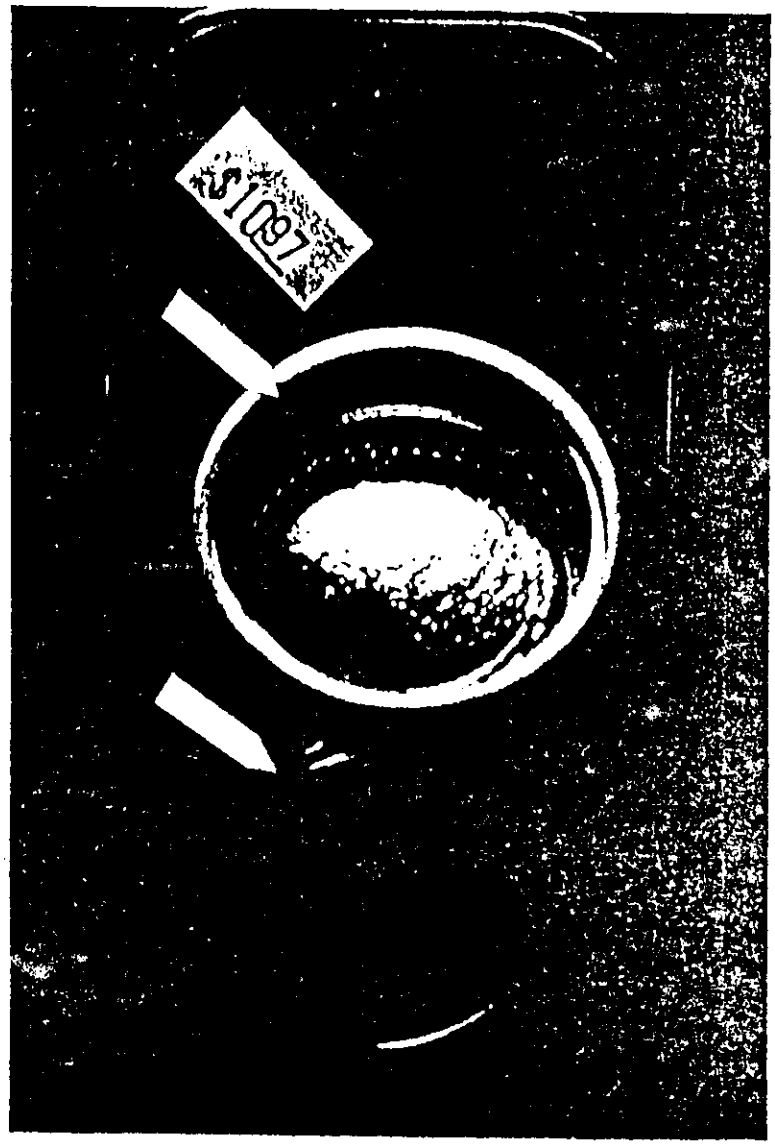
FORMBY'S® CONDITIONING FURNITURE REFINISHER. Product sold by L&F Products.

PICTURE 14



Top view of RED DEVIL® PAINT AND VARNISH REMOVER Package. Package closure system includes a metal-shelled child-resistant closure.

PICTURE 15



Top view of FORMBY'S® CONDITIONING FURNITURE REFINISHER Package. Package closure system includes a metal-shelled child-resistant closure and a metal outside plug.

PLASTICS CORPORATION

ATTACHMENT I

April 29, 1994

Mr. John G. Wood
Manager, Regulatory Affairs
DowBrands
9550 Zionsville Road
PO Box 68511
Indianapolis, IN 46268-0511

RE: CPSC Proposed CR Regulation Changes – CFR Vol. 59, No. 54, Monday, March 21, 1994

Dear John:

You have inquired about the development time of a new Sr. friendly child resistant overcap should existing designs not function to the proposed Sr. friendly protocol, (March 21, 1994).

It is difficult to determine a set time to develop an overcap due many variables. However, our best estimate, based on starting in August of 94, to be in production with a new overcap that is Sr. friendly would be the Fourth Quarter of 1996.

If you have any questions, please feel free to contact me.

Sincerely,

Brett J. Kaufman
Product Manager - Overcaps

[redacted]

cc: Doug Bell – VP Sales & Marketing, Berry Plastics

SUNBEAM PLASTICS

SUNBEAM PLASTICS
3345 Kansas Road
Evansville, IN 47711-4611
Fax 812-867-6586
Telephone 812-867-6671

May 3, 1994

Mr. Evan Hutchison
Director of Engineering
L&F Products
225 Summitt Avenue
Montvale, NJ 07645

ATTACHMENT II

Dear Mr. Hutchison:

Thank you for the opportunity to supply child-resistant packaging to L&F Products. Sunbeam is a company built on developing and manufacturing safety closures for over the past twenty-three years. We supply child-resistant closure systems to many end-use markets including household chemicals (HHC), industrial chemicals, automotive, and healthcare.

Sunbeam began by supplying safety packaging to the HHC and automotive markets and today these markets are a significant portion of our product development and business. Attached is a partial list of end-use markets, Sunbeam customers, and brand names.

Over the past five years we have focused development efforts toward closure systems for metal packaging. We have learned first hand the challenges of containing solvents and petroleum distillates. Sunbeam has available, in commercial quantities, two products for metal cans.

1) ***1-1/8" Beta FG***

Description - Two-piece plastic push and turn FG closure wherein the inner-cap is molded from PET plastic.

Status - Production molds and equipment in-house and running since November, 1992. Shipping to many customers.

***Limitation -** PET resin is not compatible with all solvents currently packaged in metal cans.

2) ***28mm TipLoK***

Description - Two-piece squeeze and turn CR dispensing closure. The stationary portion (base) is molded from LDPE and actually snaps into the metal can opening. The reclosing member (TIP) is molded from polypropylene.

Status - Production molds and equipment ready. No customers qualified. Market development phase.

***Limitation -** The olefin resins used within the TipLoK are not compatible with all solvents currently packaged in metal cans.

Sunbeam has two other closure systems under development for metal can packaging. One of which is a joint venture with a metal closure manufacturer wherein the inner cap of this tool-assisted push and turn will be metal. This product was required to offer something which would be compatible with all solvents.

Developments for Metal Cans

1) ***33mm Can LoK***

Description - Two-piece squeeze and turn removable closure and fitment assembly designed to snap into metal cans. The metal can opening must be developed in commercial quantities.

Status - This product is under development. Full commercial capability is in twelve to twenty-four months.

***Limitation-** The Can LoK uses the same materials as TipLoK (listed above) and has the same compatibility limitations.

2) ***1 1/4" InterLoK***

Description - Two-piece push and turn with tool-assist features allowing opening by older-adults. Joint venture with Ellisco/International Tool where they produce the metal inner-cap.

Status - This product is under development. Full commercial availability is in twelve to twenty-four months. As the closure is merely a component of the package, the actual date it could be implemented and approved for use in full production is dependent upon all others.

***Limitation -** The metal inner fits existing neck finishes and will be compatible with the products/solvents as other metal packaging.

We look forward to discussing these and other new products further and offer our development capability to introduce user-friendly safety packaging.

Sincerely,

Jeffrey C. Minnette
Business Unit Manager
Regulated Markets

JCM/rlb

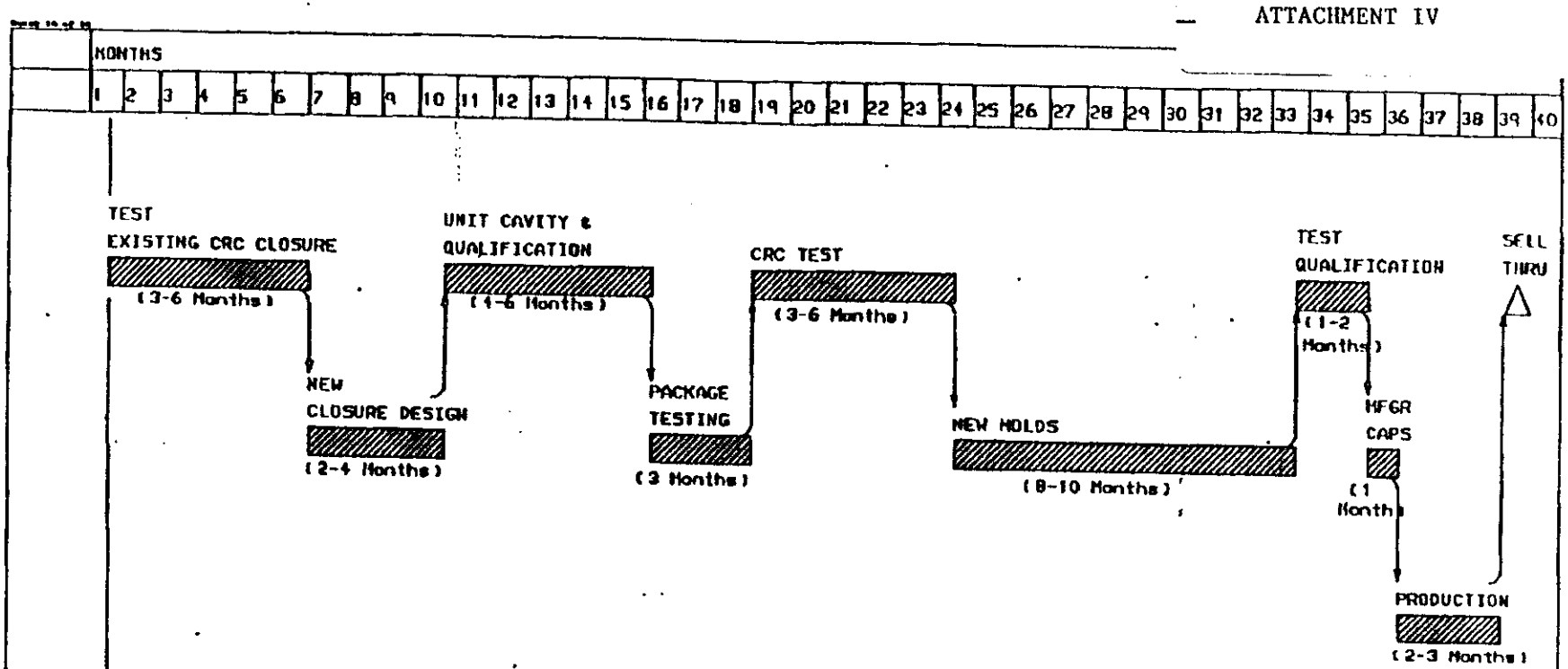
cc: Alan Bodker, Steve Hinden, Jerry Syrek - L&F Products
Randall Julian, Augie Rojas, Carl VonOhlsen - Sunbeam Plastics

ATTACHMENT III

CSMA
RESULTS OF SENIOR PANEL TESTING
50 ADULTS TESTED PER PACKAGE

CLOSURE TYPE	OLDER ADULT EFFECTIVENESS	FAMILIARIZATION PERIOD (5 MINUTES) FAILURE TO OPEN: GAVE UP TRYING	FAMILIARIZATION PERIOD (5 MINUTES) FAILURE TO OPEN: EXCEED TEST TIME	TOTAL FAMILIARIZATION FAILURES	TEST PERIOD (1 MINUTE) FAILURE TO OPEN: GAVE UP TRYING	TEST PERIOD (1 MINUTE) FAILURE TO OPEN: EXCEED TEST TIME	TEST PERIOD (1 MINUTE) FAILURE TO RESECURE	TEST PERIOD (1 MINUTE) TOTAL TEST FAILURES	TOTAL ACCUMULATIVE FAILURES	AVERAG GAVE TRYI
Plug Fit Twist-and Lock Dispensing Closure	88%	4	None	4	None	1	1	2	6	4 @
Plug Fit Tabbed Closure	86%	5	None	5	None	1	1	2	7	5 @
Plug Fit Liquid Dispensing Closure	82%	8	None	8	None	None	None	None	8	8 @
Continuous Thread Single Shell Dispensing Closure	92%	2	None	2	1	1	None	2	4	3 @
Continuous Thread Double Shell Closure	86%	5	None	5	2	None	None	2	7	7 @
38 MM CT Locking Lug Closure	48%	18	None	18	1	5	2	8	26	19 @
Aerosol W/ Child Resistant 21 CRT Over Cap	84%	12	None	12	2	4	None	6	18	14 @
32 Oz Bottle W/ 33MM CT Push & Turn Closure	42%	24	None	24	2	2	1	5	29	24 @
16 Oz Bottle W/ 28-400 CT Push & Turn Closure W/ Angle Neck	76%	10	None	10	None	1	1	2	12	10 @
34 Oz Canister W/ Pinch & Pull Closure	54%	16	None	16	2	1	4	7	23	16 @
12 Oz Metal Canister W/ Press Down Flip-up Closure	80%	4	None	4	1	None	None	1	5	5 @
16 Oz Bottle W/ 28-400 CT Push & Turn Closure	70%	10	1	12	1	1	1	3	15	11 @

ATTACHMENT IV



CHILD RESISTANT CLOSURE DEVELOPMENT TIMING
(DATE OF MANUFACTURE) -- 37 MONTHS

*Assumption: No Design Failure

DESCRIPTION

△MILESTONE

CRITICAL

CHILD RESISTANT CLOSURE DEVELOPMENT TIMETABLE

SURETRAK	NEW CRC CAP DEVELOPMENT

Child Related Research, Inc.

May 5, 1994

ATTACHMENT V

Ms. Brigid D. Klein, Attorney
Chemical Specialities Manufacturers Association, Inc.
1913 Eye Street, N.W.
Washington, D.C. 20006

Dear Brigid,

We appreciate the opportunity to express to you some of the concerns that we have as a testing agency concerning the high volume of testing that will need to be conducted once a final rule has been published, and the limit of one year from the date of final regulations to accomplish this.

Our experience over the past three years has been that not many of the current packaging will pass the proposed protocol without some type of modification or total redesigning. This is especially true of the household chemical manufactures, i.e. drain cleaners, swimming pool chemicals, cleaning and disinfectant agents. Most of these types of closures are difficult by design due to the high toxicity of their contents.

We have clients who currently have 30 to 50 different re-closeable CR packages, ranging in all sizes and shapes. These will need to be tested with senior adults and then taken to children for verification of proper resecuring. Many of these same companies also have non-closable CR packages that will need to be tested as well. Those packages that will pass the proposed protocol the first time around are one thing, but the many packages that will require modification can take several months of re-designing and re-testing before they pass.

Most manufacturers are aware of the tremendous time, money and resources that will have to be dedicated to the testing and designing of current and new packaging. The question has been asked, "They have known about this revision for several years, why have they waited until now to begin doing something about it?" The manufacturers have been aware of these changes but have been reluctant to begin testing because they know that there is a good chance they will have to re-test when the final regulation is published. This is because of changes in the testing procedures.

Because of this and other factors, we believe there will be little testing conducted until a final regulation is published. Our main concern is with the bottleneck that will occur, due to the fact of everybody having to have their packages tested within the one year period. We believe this is a valid concern and should not be taken lightly.

Again, we appreciate the opportunity to express our concerns. If we can be of further help, please let us know.

Best regards,

Mike Buie

Michael S. Buie
Executive Vice President

4141 South Highland Drive • Suite 308 • Salt Lake City, Utah 84124 • (801) 277-3677 • Fax # (801) 277-3633

SUNBEAM PLASTICS

SUNBEAM PLASTICS
3245 Kansas Road
Evansville, IN 47711-9611
Fax 812-867-6861
Telephone 812-867-6671

November 15, 1994

Chairman Ann Brown
Consumer Product Safety Commission
Washington, D.C. 20207

Dear Chairman Brown:

The purpose of this letter is to clarify Sunbeam's existing and new closure availability for end products used by the Chemical Specialties Manufacturers Association member companies.

Sunbeam does not have available concepts which are compatible with all products packaged in metal cans. Specifically, Sunbeam does not produce nor have concepts for closures for child resistant aerosol overcaps. In addition, we do not have available closures for threaded metal cans which are chemically compatible with all products.

Sunbeam is committed to meeting the needs of the child resistant closure market and will continue to pursue projects for a wide variety of end-use markets.

Once again, thank you for the Chairman's Award to Sunbeam. It is truly a tribute to the work of all Sunbeam Plastics associates.

Sincerely,

Jeffrey C. Minnette
Unit Manager
Regulated Products

JCM/rlb

\\bb\jm\cpsc.ltr

A RAYOVAC COMPANY

Attachment III

1913 Eye St. N.W.
Washington, DC 20006

202 / 872-8110
Telefax 202 / 872-8114

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

PHASE-IN OPTION

Because of the difficulty in meeting the statutorily mandated one year effective date, the Consumer Product Safety Commission (CPSC) Staff has asked for suggested phase-in options for the protocol change. In response to this request, the Chemical Specialties Manufacturers Association (CSMA) suggests that the Commission adopt a phase-in approach for Poison Prevention Packaging Act (PPPA) substances, 16 C.F.R. § 1700.14, where it is technically feasible, practicable and appropriate[1], and where confirmed reports based on data from the American Association of Poison Control Centers annual report and NEISS study of children's poisoning incidents support such a change. It is our belief that the proposed CSMA Phase-In approach would address the primary CPSC concerns of maintaining consumer safety, while simultaneously allowing industry to effectively adopt new CPSC testing standards in a thorough yet expedient manner that is technically feasible.

This approach is consistent with the regulations contained in 16 C.F.R. § 1700.3, which require that the Commission consider ". . .(2) available scientific, medical, and engineering data concerning childhood accidental ingestions, illness, and injury caused by household substances; (3) the manufacturing practices of the industries affected by the act; and (4) the nature and use of the household substance."

Based on data obtained through a CSMA Freedom of Information Act Request, it is clear that there is a substantial problem with accidental ingestions of pharmaceutical products. We recommend that pharmaceutical products be regulated concurrently with chemical specialty products currently packaged in HDPE packaging with continuous-threaded closures provided that there are sufficient qualified (i.e., compatible) closures commercially available in

---

1 "Technically feasible" means that package designs that would meet the requirements of 16 C.F.R. § 1700.15(b), and that would be suitable for use with the products subject to the rule, are or can be available. A standard is "practicable" when special packaging for the products covered by the rule is adaptable to modern mass production in assembly line techniques. That special packaging is "appropriate" is established by showing that special packaging can be available in forms that are not detrimental to the integrity of the substance and do not interfere with its storage or use. 55 Federal Register 40658 citing S. Rep. No. 91-345, 91st Cong. 2d Sess. 10 (1970).

sufficient quantities (with pharmaceutical products having priority for the available closure systems.)

In our written comments, and meetings with Commission staff, it was clearly demonstrated that there are certain chemical specialty products that cannot comply with the PPPA protocol revision within one year (technically feasible, practicable and appropriate closure systems do not exist.) For those product forms only, the Commission would not apply the revised senior adult test protocol until it is demonstrated that there are qualified (i.e., technically feasible, practicable and appropriate) closure systems available. CSMA strongly suggests that the Commission establish a voluntary special packaging phase-in task force for assistance in gathering information for ultimate conversion of these difficult closure systems and to advise in future phase-in activities.

Implementation Steps

1. Approve revised protocol (December, 1994).

2. Establish voluntary special packaging phase-in task force.

3. Phase-in implementation - pharmaceutical products and chemical specialty products currently packaged in HDPE packaging with continuous-threaded closures.

4. Keep current adult protocol in effect for those products to be phased-in later.

5. In one year, CPSC will hold a hearing to request information on status of availability of new generation closures that can pass the new senior adult protocol.

6. When a sufficient amount of special packaging for a product class is available, issue final regulation to bring in additional products.

7. Repeat process as necessary.

Justification

1. Complies with statutory requirement of technically feasible, practicable and appropriate.

2. CPSC will have already acted on the protocol change.

3. Provides for orderly phase-in and fairness to avoid having a one year deadline imposed where special packaging is not yet available.

4. Permits testing of closures under a final senior adult test protocol, rather than under a proposed protocol.

5. Accomplishes the Commission's goals.

10/20/94

Founded 1914

1913 Eye St. N.W.
Washington, DC 20006

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

202 / 872-8110
Telefax 202 / 872-8114

PHASE-IN OPTION

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10/20/94