United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

CPSC/OFFICE OF THE SECRETARY
1999 MAY 25 P 3 5

VOTE SHEET

DATE: MAY 21 1999

TO : The Commission
Sadye E. Dunn, Secretary

FROM : Jeffrey Bromme, General Counsel
Stephen Lemberg, Assistant General Counsel
Patricia M. Pollitzer, Attorney

SUBJECT: Final PPPA Rule Requiring Child-Resistant Packaging for Household Products Containing Methacrylic Acid

Attached is a staff briefing package recommending that the Commission issue a final rule requiring child-resistant packaging under the Poison Prevention Packaging Act for household products containing more than 5 percent methacrylic acid in a single package. Tab E of the package contains a draft Federal Register notice.

Please indicate your vote on the following options.

I. Approve the Federal Register notice as drafted.

(Signature) _____ (Date) _____

II. Approve the draft Federal Register notice with the following changes (please specify).

_____

_____

_____

(Signature) _____ (Date) _____

NOTE: This document has not been reviewed or accepted by the Commission.
Initial HL Date 5/21/99

CPSA 6 (b)(1) Cleared

____No Mfrs/PrvtLblrs or Products Identified

III. Do not approve the draft Federal Register notice.

(Signature) (Date)

IV. Take other action (please specify).

(Signature) (Date)

Attachment

Briefing Package

Final Rule to Require Child-Resistant Packaging for Household Products Containing More than 5 Percent Methacrylic Acid in a Single Package

For Information Contact:

Susan Aitken, Ph.D.
Directorate for Epidemiology & Health Sciences
(301) 504-0477 ext. 1195

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EXECUTIVE SUMMARY

Methacrylic acid is used as a primer for cleaning, degreasing, dehydrating, and etching fingernails prior to applying artificial nails. Although the U.S. Food and Drug Administration regulates cosmetics such as nail products under Section 201 of the Federal Food, Drug, and Cosmetic Act, household cosmetic products can also be subject to the special packaging requirements of the U.S. Consumer Product Safety Commission (CPSC) under the Poison Prevention Packaging Act (PPPA). The Commission proposed a special packaging standard for liquid household products containing more than 5 percent methacrylic acid on December 30, 1998.

Staff received five comments on the proposed rule. Three comments supported the rule on the grounds that nail primers containing methacrylic acid caused serious injury to young children in the home, and a requirement for child-resistant (CR) packaging was needed to address that hazard. Two comments did not dispute the proposed rule, but pointed to the hazard of methacrylic acid to professional cosmetologists in the workplace.

Staff previously provided evidence that nail primers containing methacrylic acid cause serious personal injury or illness to children less than five-years-old by virtue of their packaging. Acute effects range from slight irritation to severe corrosive injury on contact of methacrylic acid in nail primers with skin, eyes, or mucous membranes. Nail primers containing methacrylic acid currently are not in CR packaging. However, the data support the conclusion that a special packaging standard for household products containing methacrylic acid is technically feasible (producible), practicable (adaptable to mass production techniques), and appropriate (chemically compatible with the product). Staff analysis indicates that the rule will not have a significant economic effect on a substantial number of small businesses and will not have a significant impact on the environment.

The staff recommends that the Commission issue a final rule requiring CR packaging for liquid household products containing more than 5 percent methacrylic acid (weight/volume) in a single package. Staff recommends an effective date of one year.

United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: MAY 21 1999

TO : The Commission
Sadye E. Dunn, Secretary

THROUGH : Jeffrey S. Bromme, General Counsel JSB
Pamela Gilbert, Executive Director PG

FROM : Ronald L. Medford, Assistant Executive Director for Hazard Identification RLM
Susan C. Aitken, Ph.D., Pharmacologist, Division of Health Sciences SCA

SUBJECT : Special Packaging Standard for Household Products Containing Methacrylic Acid

I. INTRODUCTION

Methacrylic acid (MAA) is a widely used chemical intermediate in the manufacture of resins, paints, adhesives, paper, polishes, plasticizers, and dental fillings. Exposure to MAA is known to cause serious injury due to its corrosive activity on contact with skin, eyes, and mucous membranes. In the household and in professional beauty salons, MAA is used as a primer for cleaning, degreasing, dehydrating, and etching fingernails prior to applying artificial nails. Although most of the nail primers containing MAA are labeled "For Professional Use Only," injury reports indicate that these products are used in the household and that young children access them and experience serious personal injury or illness as a consequence of that access. On December 30, 1998, the Commission issued a proposed rule (TAB A) that would require child-resistant (CR) packaging for liquid household products containing more than 5 percent (weight/volume) MAA in a single package. At this time, nail primers are the only household products known to contain MAA at this level.

II. DISCUSSION

A. Toxicity and Updated Injury Data

Staff provided detailed toxicity and human injury data to the Commission in a briefing package dated December 15, 1998 (summarized below). The data from available injury data bases and case reports from the medical literature cumulatively established that young children access nail primers containing MAA, that these nail primers are found in the home, and that these nail primers cause serious personal injury and harm to children less than 5-years-old. No new information affecting the staff's conclusions concerning toxicity and injuries has emerged.

The medical literature contained two examples of serious dermal or gastrointestinal (GI) burns to young children due to nail primers containing MAA. The American Association of Poison Control Centers (AAPCC) reported 467 exposures, including 341 poisonings (ingestion, ingestion and dermal), 11 ocular exposures, and 115 dermal exposures to children less than 5-years-old in 1996 and 1997. Approximately 90 percent of poisonings occurred in the home (the child's residence or another personal residence). Detailed case reports included at least three serious injuries.

The U.S. Consumer Product Safety Commission's (CPSC) databases contained 85 records of poisonings or burns due to MAA-containing nail primers between January 1, 1988 and September 30, 1998. Five of these reports documented serious injuries on ingestion or dermal exposure to MAA in nail primers. Since that date, three additional injuries have been reported to the CPSC. None of the three children was hospitalized. One exposure was an attempted ingestion of a nail primer that was not confirmed to contain MAA. The other two children suffered burns on their legs after spilling bottles of nail primers known to contain MAA. In close agreement with the AAPCC data, approximately 83 percent of exposures reported to the CPSC occurred in the home.

B. Public Comments

Staff mailed a letter inviting comment and a copy of the Federal Register Notice of Proposed Rulemaking to approximately 150 firms or trade associations involved in the production or sale of nail cosmetic products. The Commission received five comments in response to the proposed rule (TAB B).

Support for the Proposed Rule

Comment (CP99-1-3)

The American Academy of Pediatrics expressed support for the proposed rule on the grounds that nail care products containing MAA are commonly used in the home and have the potential to cause permanent disability or death in children. The Academy noted that MAA-containing nail products were the cause of 759 reports of exposure to the American Association of Poison Control Centers (AAPCC) between 1993 and 1995. More than 74 percent of these reports involved children less than 6-years-old.

Comment (CP99-1-4)

The American Beauty Association (ABA), a non-profit trade association representing over 200 manufacturers selling more than 80 percent of professional-use beauty salon products, commented favorably on the rule. The ABA indicated that the Commission engaged in a "full and fair analysis" in the proposed rule, and fairly weighed the hazard to children against the practicality and feasibility of protecting children from that hazard.

Comment (CP99-1-5)

The Methacrylate Producers Association (MPA), an association of manufacturers of MAA and MAA esters, also expressed support for the rule. The MPA noted that, although some nail products containing MAA may be intended for purchase by professional beauticians, these products are also widely available and used by consumers. Further, the MPA observed that use of these nail products in the home appeared to be an increasing trend and the need for CR packaging in the home environment was clear.

Health Hazards in the Workplace

Comment (CP99-1-1)

Beatrice Kaye Cosmetics commented that MAA and related acrylate chemicals pose a serious health risk to both professional cosmetologists and their patrons.

Response

The health risks that are discussed in this comment concern air quality and potential systemic toxicity (i.e., organ damage) due to exposure to acrylates in the workplace via inhalation and other routes. The Commission has no jurisdiction over cosmetic products except to require CR packaging for cosmetics used in the household, and so the staff has forwarded information regarding workplace exposure to the Occupational Safety and Health Administration. While CR packaging could conceivably address inhalation risks to children by limiting their access to a product, it does not impact adult access or adult occupational health risks. Therefore, this comment is not pertinent to the proposed rule.

Comment (CP99-1-2)

No Lift Nails, a manufacturer of MAA-containing nail primers, expressed concern that no CR closures that would fit a 15 millimeter (mm) bottle finish are available. In order to prevent injuries to professional cosmetologists from spillage, the commenter suggested that the Commission recommend a maximum container size of one-half ounce and require primer containers to have a small orifice. The commenter had also previously suggested that the Commission could limit the possibility of spillage through a requirement for restricted flow.

Response

A wide variety of neck inserts that effectively reduce orifice size are available. Many of these are useable for containers with 20 mm finishes and would serve the commenter's purpose. However, under the PPPA, the Commission cannot prescribe "specific packaging designs, product contents, package quantity, or, with the exception of authority granted in section 4(a)(2) of this Act, labeling." [Section 3(d) 15 U.S.C. 1472]. Therefore, the Commission cannot restrict the package size of MAA-containing nail primers.

Packaging designed and constructed to meet certain standards is regarded as "special packaging" under section 2(4) of the PPPA. One of these is a restricted flow feature. The Commission requires non-emulsion liquid furniture polish containing 10 percent or more mineral seal oil and/or other petroleum distillates and having viscosity less than 100 Saybolt Universal Seconds (SUS) at 100°F to meet criteria for restricted flow. [16 CFR 1700.14(a)(2)]. Restricted flow is defined in 16 CFR 1700.15(d) as "..the flow of liquid is so restricted

that not more than 2 milliliters of the contents can be obtained when the inverted, opened container is shaken or squeezed once or when the container is otherwise activated once."

However, the staff believes that the restricted flow standard would not be appropriate for the intended use of MAA in nail primers because volumes much smaller than two milliliters (ml) are applied to nails at a single use, and because applicators are commonly inserted into the nail primer containers. The staff identified no current restricted flow packaging that is compatible with the use of applicators.

C. Level for Regulation

Both animal and human data indicate MAA can cause acute effects ranging from slight irritation to severe corrosive injury on contact with eye, skin, or mucous membranes of the GI and respiratory tracts. Severity of injury is concentration-dependent. The proposed rule set the level for regulation at more than 5 percent MAA (weight/volume) in a single package. No comments were received on this level.

D. Regulatory Flexibility Issues

The public comments on the proposed rule provided no additional information regarding potential adverse impact on small businesses. One leading manufacturer of nail primers containing MAA privately communicated intent to change bottles from glass to plastic and bottle finish from 15 to 20 mm in order to be more compatible with existing 20 mm CR plastic closures. This manufacturer also intends to use plastic neck inserts to decrease the orifice size. Another manufacturer is phasing in a fiber applicator tip pen-like device that would be exempt from CR requirements. Other manufacturers are forming a consortium through the ABA and Nail Manufacturers' Council (NMC) to fund development of new molds for CR closures. The staff concluded that a requirement for special packaging of liquid MAA-containing products will not have a significant economic effect on a substantial number of small businesses or other small entities.

E. Technical Feasibility, Practicability, and Appropriateness

A finding of technical feasibility may be made when technology exists or can be readily developed to produce packaging corresponding to PPPA standards (general requirements, effectiveness specifications, reuse, and restricted flow). A finding of practicability may be made when packaging complying with the standards can utilize modern mass production and

assembly line techniques. A finding of appropriateness may be made when complying packaging will adequately protect the integrity of the substance and not interfere with its intended storage or use.

CR and senior-friendly closures, including a 20 mm continuous-threaded plastic closure (without insert for applicator) and a 28 mm continuous-threaded plastic closure (with an insert for an applicator) are available and are now in mass production. Staff determined that that data support a finding that production of a 20 mm CR and senior-friendly closure with an insert for an applicator is technically feasible, practicable, and appropriate.

Glass and plastic bottles with 20 mm finishes are available and currently used for MAA-containing nail primers. Plastic neck inserts to decrease the orifice size of these bottles are also available, and at least one such device is in now in use with MAA. At least one manufacturer plans to convert his current packaging using the above available options for closures, bottles, and inserts.

Staff concluded that available data support the finding that it is technically feasible, practicable, and appropriate to produce special packaging for products that contain more than 5 percent MAA. Staff received no comments on the proposed rule that dispute this conclusion.

F. Effective Date

The PPPA provides that no regulation shall take effect sooner than 180 days or later than one year from the date such regulation is issued unless the Commission determines that an earlier effective date is in the public interest. The Commission proposed an effective date of one year in the proposed rule. A year provides time to produce commercial quantities of the available 20 and 28 mm CR and senior-friendly closures, adjust assembly lines to a different bottle size, and conduct testing following the PPPA protocol. No comments were received on an effective date of one year.

G. Exemption

The proposed rule recommended exempting a MAA-containing nail primer package resembling a plastic marker pen with a fiber applicator tip from the requirement to comply with a special packaging standard. The pens contain a wicking material, ensuring that no free liquid is available and very small amounts of liquid can emerge only at the tip. Staff found no evidence of injury to young children from these devices at the time the proposed rule was issued and has found no evidence since that time. No comments were received on the proposed exemption.

III. OPTIONS

The Commission may issue a rule requiring special packaging for liquid household products containing more than 5 percent MAA in a single package if the Commission finds that:

1) special packaging is required to protect young children from serious personal injury or illness from handling, using, or ingesting the product; and
2) special packaging is technically feasible, practicable, and appropriate.

The Commission may decline to issue a special packaging rule if it is unable to make these findings.

IV. RECOMMENDATION

Methacrylic acid is a corrosive substance contained in artificial nail primers. The medical literature and available injury records document serious burns to children less than 5-years-old resulting from household use of this product. Nail primers containing methacrylic acid are not now in CR packaging. Staff determined that CR packaging is available or can be developed.

The staff recommends that the Commission issue a final rule requiring CR packaging for liquid household products containing more than 5 percent (weight/volume) methacrylic acid in a single package. The staff also recommends that dispensers resembling plastic marker pens in which methacrylic acid is contained by an internal absorbent material, such that no free liquid is within the dispenser and the methacrylic acid emerges only from the tip of the dispenser, be exempt from the requirement for a special packaging standard. A draft FR notice for a final rule is at TAB E.

TAB A

certificated for operation in the United States.

Explanation of the Provisions of the Proposed AD

Since an unsafe condition has been identified that is likely to exist or develop in other I.A.M. Model Piaggio P–180 airplanes of the same type design registered in the United States, the FAA is proposing AD action. The proposed AD would require inspecting the upper and lower engine nacelle inner panels for any loose or partially detached inner film, and removing any loose or partially detached inner film. Accomplishment of the proposed inspection and possible removal would be required in accordance with Piaggio Service Bulletin (Mandatory) No.: SB–80–0101, Original Issue: May 6, 1998.

Compliance Time of the Proposed AD

Although the reduced engine power that would result if loose film particles accumulated on the engine inlet screen would only be unsafe during flight, this condition is not a result of the number of times the airplane is operated. The loose film occurs over time because of weather and climate conditions. For this reason, the FAA has determined that a compliance based on calendar time should be utilized in this AD in order to assure that the unsafe condition is addressed on all airplanes in a reasonable time period.

Cost Impact

The FAA estimates that 5 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 7 workhours per airplane to accomplish the proposed inspection and film removal, and that the average labor rate is approximately $60 an hour. There are no parts required to accomplish the proposed AD. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $2,100, or $420 per airplane.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive (AD) to read as follows:

Industrie Aeronautiche E Meccaniche: Docket No. 98–CE–97–AD.

Applicability: Model Piaggio P–180 airplanes, all serial numbers, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated in the body of this AD, unless already accomplished.

To prevent the accumulation of loose particles on the engine inlet screen caused by film delamination, which could result in reduced engine power and possible loss of airplane control, accomplish the following:

(a) Within the next 6 calendar months after the effective date of this AD, inspect the upper and lower engine nacelle inner panels for any loose or partially detached inner film, in accordance with the ACCOMPLISHMENT INSTRUCTIONS section of Piaggio Service Bulletin (Mandatory) No.: SB–80–0101, Original Issue: May 6, 1998. Prior to further flight after the inspection, remove any loose or partially detached inner film in accordance with the service bulletin.

(b) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(c) An alternative method of compliance or adjustment of the compliance times that provides an equivalent level of safety may be approved by the Manager, Small Airplane Directorate, 1201 Walnut, suite 900, Kansas City, Missouri 64106. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Small Airplane Directorate.

(d) Questions or technical information related to Piaggio Service Bulletin (Mandatory) No.: SB–80–0101, Original Issue: May 6, 1998, should be directed to I.A.M. Rinaldo Piaggio S.p.A., Via Cibrario, 4 16154 Genoa, Italy. This service information may be examined at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Note 3: The subject of this AD is addressed in Italian AD 98–208, dated June 9, 1998.

Issued in Kansas City, Missouri, on December 22, 1998.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–34581 Filed 12–29–98; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Requirements for Child-Resistant Packaging; Household Products Containing Methacrylic Acid

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule.

SUMMARY: The Commission is proposing a rule to require child-resistant ("CR") packaging for liquid household products containing more than 5 percent or more methacrylic acid (weight-to-volume) in a single package. The Commission has preliminarily determined that child-resistant packaging is necessary to protect children under 5 years of age from serious personal injury and serious

illness resulting from handling or ingesting a toxic amount of methacrylic acid. The Commission is specifically concerned about nail care products containing methacrylic acid, the only household product the Commission has confirmed to contain methacrylic acid. The Commission takes this action under the authority of the Poison Prevention Packaging Act of 1970.

DATES: Comments on the proposal should be submitted no later than March 15, 1999.

ADDRESSES: Comments should be mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814–4408, telephone (301) 504–0800. Comments may also be filed by telefacsimile to (301) 504–0127 or by email to cpsc-os@cpsc.gov.

FOR FURTHER INFORMATION CONTACT: Susan Aitken, Ph.D., Division of Health Sciences, Directorate for Epidemiology and Health Sciences, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504–0477 ext. 1195.

SUPPLEMENTARY INFORMATION:

A. Background

1. Relevant Statutory and Regulatory Provisions

The Poison Prevention Packaging Act of 1970 ("PPPA"), 15 U.S.C. 1471–1476, authorizes the Commission to establish standards for the "special packaging" of any household substance if (1) the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance and (2) the special packaging is technically feasible, practicable, and appropriate for such substance.

Special packaging, also referred to as "child-resistant" ("CR") packaging, is (1) designed or constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and (2) not difficult for "normal adults" to use properly. 15 U.S.C. 1471(4). Household substances for which the Commission may require CR packaging include (among other categories) foods, drugs, or cosmetics that are "customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household." 15 U.S.C. 1471(2). The Commission has performance requirements for special packaging. 16 CFR 1700.15, 1700.20.

Section 4(a) of the PPPA, 15 U.S.C. 1473(a), allows the manufacturer or packer to package a nonprescription product subject to special packaging standards in one size of non-CR packaging only if the manufacturer (or packer) also supplies the substance in CR packages of a popular size, and the non-CR packages bear conspicuous labeling stating: "This package for households without young children." 15 U.S.C. 1473(a), 16 CFR 1700.5.

2. Methacrylic Acid

Methacrylic acid ("MAA") is used as a primer for cleaning, degreasing, dehydrating and etching fingernails before applying artificial nails. Nail products containing MAA are cosmetics under the Food Drug and Cosmetic Act ("FDCA"). According to the FDCA, "cosmetic" includes "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering appearance." 15 U.S.C. 321(i). MAA is also used as a chemical intermediate in making resins, paints, adhesives, paper, polishes, plasticizers and dental fillings. However, the Commission does not believe that these products would be affected by the proposed rule because, in the process of manufacturing these products, the bulk of MAA becomes polymerized and is no longer in the form of the monomer MAA.

Nail primers are used to help acrylic overlays adhere to the nail surface. Not all nail primers contain MAA. Primers that do contain MAA may have as much as 100 percent MAA, but some may have other ingredients. Of the primers examined by the staff, those that do contain MAA have at least 50 percent MAA. Most of the nail primers that contain MAA are labeled "For Professional Use Only." They are generally distributed through wholesale distributors directly to nail salons and to retail beauty supply stores. Some of these retail stores sell to both professionals and consumers. To obtain samples, CPSC staff visited several beauty supply retail stores, and purchased four nail primers containing MAA. They were packaged in small bottles containing ¼ oz. to ½ oz. of primer. All were sold individually packaged, none were CR and all were labeled "Professional Use Only" or "For Professional Use Only." The staff obtained an additional primer that was confirmed to contain MAA by mail order purchase. It came in a non-CR bottle labeled "For Professional Use Only."

According to industry sources, there may be as many as 50 nail primer suppliers. Approximately 90 percent of nail primers marketed to professionals contain MAA. The Commission is aware of 13 companies that market or have marketed MAA-containing nail primers.

Based on industry estimates, the CPSC staff estimates annual unit sales of MAA-containing nail primers at about 1.0 to 1.3 million units in ¼ oz., ½ oz. and larger sizes. The annual retail value of these units amounts to $4–6.5 million. The wholesale value of these products is about $2.9 to $4.6 million based on a 40 percent mark-up typical of the industry.

Spokespersons for the industry could not estimate the number of consumers using MAA-containing primers at home. It is clear, however, from the incident data discussed below that these products are used in the household, and children are obtaining access to them. The ability of CPSC staff to purchase these primers at retail stores and by mail also shows that these products are readily available for consumers to purchase and bring home.

B. Toxicity of Methacrylic Acid

MAA is readily absorbed through mucous membranes of the lungs and gastrointestinal ("GI") tract as well as through the skin. It is rapidly distributed to all major tissues, with the highest concentrations in the liver and kidneys. It is a corrosive, meaning that, when it comes into contact with living tissue, it causes destruction of tissue by chemical action. 15 U.S.C. 1261(i).

MAA's effects are similar to those of other acids. Dermal burns can destroy the surface of the epithelium and submucosa with damage to blood vessels and connective tissue. Inhaling acid vapors may produce nasal irritation, salivation, conjunctival irritation, difficulty breathing, pleuritic chest pain, and bronchospasm. Ingestion generally produces mild to severe oral and esophageal burns and GI bleeding, perforation, edema, necrosis, stenosis (narrowing of the GI passage) and fistulas (abnormal passages or outpocketings). Other intestinal injuries may also occur. Areas of stricture may develop about 3 weeks after ingestion. Eye exposure may cause pain, swelling, corneal erosions, and blindness.

C. Incident Data

The staff reviewed several sources for information of adverse health effects

from nail products containing MAA. These sources are published reports in the medical literature, the American Association of Poison Control Centers ("AAPCC"), the FDA Cosmetic Voluntary Registration Program ("CVRP"), and reports from the injury surveillance databases maintained by the Commission.

1. Medical Literature

A recent article in the medical literature analyzed data from the Toxic Exposure Surveillance System ("TESS") for 1993 through 1995. The American Association of Poison Control Centers ("AAPCC") collects reports of exposures to toxic chemicals (drugs, household products, poisonous plants, etc.) made to participating poison control centers within the United States in the TESS data base. The TESS data base contains 759 reports of exposures to MAA-containing nail products. Most of the exposures to children less than 6-years-old occurred in the home and involved either ingestion or both dermal contact and ingestion. Children less than 6-years-old accounted for 564 exposures. Two-year-old children were most at risk (approximately 330 exposures). Approximately 10 percent of young children suffered moderate to major injuries.[1]

A second recent article reviewed the hazard of nail care products, among them nail primers containing MAA, and reported the medical consequences of ingestion of and/or dermal exposure to primers in two children less than 5-years-old and one adult. In the first case, a 21-month-old male accidentally ingested approximately 3–5 ml of a product containing at least 98 percent MAA. The child began drooling, gagging, and vomiting. Physicians at the emergency room ("ER") of a local hospital observed that the child was in great distress on arrival 30 minutes after ingestion. He required endotracheal intubation to maintain the airway and upper GI endoscopy. The upper GI tract, pharynx, and airways showed severe tissue damage. He developed bilateral pneumonia and respiratory distress with stridor (a harsh, high-pitched respiratory sound often associated with acute laryngeal obstruction). He required positive pressure ventilation for 6 days and parenteral nutrition for 15 days. A regular diet was resumed only after he was discharged from the hospital 28 days after he was admitted. Although x-rays of the esophagus and stomach appeared normal one month after discharge, the child experienced intermittent episodes of choking and vomiting. One year later, x-rays confirmed a stricture of the esophagus. Skin burns on the lips, chin, and neck resolved without permanent scarring.

A 2½-year-old male spilled approximately 5–7 ml of a product containing at least 98.5 percent MAA onto his face, right arm, and chest. He immediately began screaming. The affected areas were immediately rinsed with water, and he was treated at a nearby hospital 20 minutes later. ER personnel noted patchy erythema of the face, chest, right arm, and flank. Blisters developed on his chest. Treatment included rinsing his body and applying silver sulfadiene and aloe to burn areas. All burn areas healed without scarring.

A 27-year-old female ingested two artificial nail products. The first contained MAA and methylethyl ketone. The second product contained ethyl methacrylate (an ester of MAA), proprietary modifiers, and polymerization accelerators. The woman arrived at the ER 30 minutes after ingestion with symptoms of lethargy and cyanosis (a bluish color of the skin). She also exhibited lesions of the pharynx, mucosal injury in the mouth and pharynx, and ulcerated areas in the upper esophagus. Areas of persistent ulceration in the esophagus were still present after 7 days. She was able to eat a normal diet only after 14 days of hospitalization. These corrosive injuries were due to the MAA as none of the other ingredients in these products were known to be corrosives.

2. CPSC Databases

CPSC has several databases for poison incidents—the National Electronic Injury Surveillance System ("NEISS") (January 1988—September 30, 1998), the Injury and Potential Injury Incident ("IPII") data base (January 1980—September 30, 1998), the In-Depth Investigations ("INDP") data base (January 1980—September 30, 1998), and the Children and Poisonings ("CAP") data base (1978–1987). The staff reviewed these databases for incidents involving nail primers.

Between 1988 and September 30, 1998, the staff identified 85 cases as exposures to nail products specifically identified as primers or as containing MAA. It is possible that other incidents may have implicated primers and that some of the primers involved in these incidents did not contain MAA.

NEISS is a stratified probability sample of ER hospitals in the United States and its territories. The staff computed both the national estimates and sampling errors for ER visits by children less than 5 years old due to exposures to nail primers. Approximately 2,723 estimated ER visits due to exposures to nail primers occurred between January 1988 and September 1998. The lower and upper 95 percent confidence limits of this estimate were 1,756 and 3,690 respectively. Hospitalization was necessary in approximately 10 percent of estimated ER visits (262). The home was the location of exposure in 83 percent of the estimated ER visits (2,272). Primers accounted for 11 of the total 15 hospitalizations associated with nail products.

The INDP files provide additional details on some of these incidents. In one incident, a 2-year-old female spilled a bottle of nail primer containing MAA when she climbed a chair to reach the container placed on a table. On opening the bottle, the child spilled about 1½ to 2 ounces on her thigh. After trying to rub it off with her hand she then rubbed her face. The child was quickly rinsed off in a shower and taken to the ER. She was treated and released. The child suffered first and second degree burns to her right thigh and both sides of her face from her eyebrows to the bottom of her cheeks.

A 2-year-old male gained access to an artificial nail kit left on a living room table. The child was about to ingest the bonding agent (primer), possibly MAA, when he spilled about one and one-half ounces on his shirt and around his mouth and nose. He began screaming, turned pale, appeared lethargic, and his eyes were described as glassy. He was immediately taken to the ER where his burns were treated. He remained in the hospital under observation for two nights, was transferred to another hospital for an endoscopy because of difficulty swallowing, and was released after a total of four nights in the hospital.

A 12-month-old male experienced chemical burns to his hands and mouth from a fingernail primer. The child removed the cap of the primer bottle, and about one ounce of the primer spilled on his hand. The child then rubbed his mouth with his hand and began drooling and frothing. He was immediately taken to the hospital. His chemical burns were treated, and he was released the same day.

[1] "Minor symptoms" means that the patient exhibited some minimal signs or symptoms that resolved rapidly. "Moderate symptoms" means the patient exhibited signs or symptoms that were more pronounced, prolonged, or of a systemic nature which usually required some form of treatment (symptoms were not life threatening and there was no residual disability or disfigurement). "Major symptoms" means the patient exhibited some symptoms that were life-threatening or resulted in disfigurement or residual disability.

3. AAPCC Data

The staff obtained AAPCC data isolating nail products containing MAA for the years 1996 and 1997. The data include 467 exposures, including 341 poisonings (ingestion, ingestion/dermal), 11 ocular exposures, and 115 dermal exposures to children less than 5-years-old. No deaths were reported. One poisoning with major medical consequences was reported in 1997. This incident is discussed below. There were 32 poisoning outcomes coded as moderate (10.7 percent) and 137 poisonings (39.3 percent) coded as having minor outcomes.

The AAPCC also provided additional information on some exposures reported to, and collected by individual poison control centers. All these exposures involved MAA-containing nail primers. All incidents except one occurred in the child's own residence or in someone else's residence. A summary of the more significant cases from the collection follows below.

In an incident coded as having a major medical outcome (1997), a 3-year-old female experienced burns to her lips and cheeks when she attempted to ingest a nail primer at a beauty salon. She also suffered an anaphylactic reaction, presumably to the MAA in the primer. She remained in a pediatric intensive care unit (ICU) for 2 days. On the third day, she was transferred to a regular bed and her open cheek blisters had healed sufficiently to allow treatment with antibiotic ointment. An endoscopy on day 4 revealed no GI burns, and she was discharged on day 5.

A 1½-year-old female experienced burns over half her chest after spilling a bottle of primer on herself. The child required outpatient treatment at a burn center for the next 3 weeks and remained in pain for much of that period. According to the parents, her physician at the Center was considering skin grafts. The burns required approximately 4 weeks to heal.

A 20-month-old female spilled some primer in the process of attempting to ingest it. Blisters formed on the skin and most of the face within 30 minutes and the child was in evident pain. The pain persisted several days, and the burns did not begin to resolve for another week. The primary physician originally recommended consultation with a plastic surgeon; however, the burns eventually healed without scarring.

4. FDA Database

The FDA's CVRP database contains four reports of injuries from nail primers. One of these reports indicates that a 2-year-old male was brought to the ER after a nail primer splashed in his face and caused burns to the cornea of the eye and the face (1988).

D. Level for Regulation

The Commission is proposing a rule that would require special packaging for household products containing more than 5 percent methacrylic acid.

At this time, there is no evidence establishing the lowest concentration or amount of MAA capable of causing severe personal injury or illness to young children. The severity of burns to a human from corrosive chemicals is dependent on duration of exposure, site of contact, area of contact, volume and concentration of the product, and the chemical characteristics of the product. These chemical characteristics include pH, physical nature, viscosity, titratable acidity or alkalinity, molarity, oxidation-reduction potential, and complexing affinity for bivalent ions. MAA is a weak organic acid closely resembling acetic acid; in terms of acidity, acetic acid is 1.3-fold stronger than MAA when concentration is expressed in percent units. The Commission arrived at a level for regulation based on mutually supportive evidence derived from a report of concentration-related skin injury in mice due to MAA, the calculated pH of various concentrations of MAA, and the effects of acetic acid on humans at various concentrations.

Human evidence does not associate exposures to commercial vinegar (4 to 6 percent acetic acid) with skin burns but suggests these concentrations cause mild skin irritation. The Toxicological Advisory Board (U.S. CPSC, 1982) similarly concluded that 5 percent acetic acid is a weak skin irritant. However, doubling the acetic acid concentration to 10 percent results in classification as a strong skin irritant. Doubling the acetic acid concentration yet again to 20 percent requires labeling as a poison under Section 3(b) of the FHSA, 16 CFR 1500.129.

Similarly, concentrations of 4.8 percent MAA cause no irritation (in aqueous solution) or only mild irritation (in acetone solution) to the skin of mice. Doubling that concentration to 9.6 percent in an acetone solution results in epithelial necrosis (tissue destruction) and adverse effects in the dermis of the skin. This degree of injury constitutes a second degree burn to the skin and can best be characterized as severe irritation. Doubling the MAA concentration again to 19.2 percent causes visible destruction to skin epithelium and injury throughout all layers of the skin, including the dermis and submucosal musculature. These skin injuries, if not overtly corrosive, border on corrosive, causing "visible destruction or irreversible alterations in the tissue at the site of contact" as defined under the FHSA, 16 CFR 1700.3(c)(3).

Increasing degrees of injury can also be predicted to the eyes with corresponding changes in MAA concentration (4.8, 9.6, and 19.2 percent). In general, acid solutions with a pH of 2.5 or above cause little damage to the eye (the lower the pH, the stronger the acid). For example, the Toxicological Advisory Board classified a solution of 3 percent acetic acid, pH 2.53, as a moderate eye irritant. A 4.8 percent solution of MAA has a pH of 2.46, and probably would also be considered a moderate eye irritant, causing reversible inflammatory changes in the eye and its surrounding mucous membranes. Doubling the MAA concentration to 9.6 percent produces a solution with a pH of 2.3. This pH has the potential to produce more serious eye injury with inflammation of the iris and opacity of the cornea. Doubling the MAA concentration yet again to 19.2 percent results in a solution of 2.15, well within the range capable of causing corrosive eye injuries.

The use of organic solvents such as acetone or ethyl acetate in MAA solutions is likely to increase the degree of injury to eyes, mucous membranes of the GI and respiratory tract, and skin. MAA is soluble in aqueous solutions only to a limited extent (10% maximum). Any concentration of MAA exceeding 9 percent would only dissolve in organic solvents such as acetone that not only cause mild irritation in their own right but exacerbate the toxic effects of MAA itself.

The actual degree of irritancy or corrosion at 1 to 20 percent concentrations would probably depend on the volume of acid in contact with tissues, the surface area and site affected, and duration of the contact. A concentration of approximately 5 percent MAA does not cause serious injury to mouse skin. It is not likely to be more than a moderate irritant to the eyes of humans, or a mild irritant to the skin of humans. It is equivalent to a 4 percent concentration of acetic acid (about the same as vinegar), that is not associated with serious personal injury or illness in young children. However, concentrations of approximately 10 percent MAA are, at the very least, severe skin irritants in a mouse model and, judging from calculated pH values, are capable of serious eye injury. The weight of the evidence indicates that solutions containing 5 percent MAA

will not cause serious personal harm or illness in young children. Because the staff is not aware of data defining the precise point between 5 and 10 percent at which injury becomes serious, the staff recommends that child-resistant packaging be required for products containing more than 5 percent MAA to protect children from potential serious injury. The Commission solicits comments on this level.

E. Statutory Considerations

1. Hazard to Children

As noted above, the toxicity data concerning ingestion of MAA demonstrate that MAA can cause serious illness and injury to children. Moreover, it is available to children in the form of nail primers that are accessible in the home. These packages are not CR.

Pursuant to section 3(a) of the PPPA, 15 U.S.C. 1472(a), the Commission preliminarily finds that the degree and nature of the hazard to children from handling and ingesting household products containing MAA is such that special packaging is required to protect children from serious illness. The Commission bases this finding on the toxic nature of MAA-containing products and their accessibility to children in the home.

2. Technical Feasibility, Practicability, and Appropriateness

In issuing a standard for special packaging under the PPPA, the Commission is required to find that the special packaging is "technically feasible, practicable, and appropriate." 15 U.S.C. 1472(a)(2). Technical feasibility may be found when technology exists or can be readily developed and implemented to produce packaging that conforms to the standards. Practicability means that special packaging complying with the standards can utilize modern mass production and assembly line techniques. Packaging is appropriate when complying packaging will adequately protect the integrity of the substance and not interfere with its intended storage or use.

The staff evaluated the packaging of ten nail primer products. Five of these nail primers contained MAA. Four of the five were packaged in 0.25 to 2 ounce brown or tinted glass bottles with 13–20 millimeter ("mm") non-CR continuous threaded ("CT") plastic closures. One was in a brown plastic bottle with a non-CR plastic closure. Three of the five packages included a built-in applicator brush, one had a separate applicator brush, and one completely lacked an applicator brush. One primer was packaged in a plastic marker pen with a fiber applicator tip, preventing any substantial flow or spillage of free liquid from the device. The staff is aware of a similar device used for an MAA-containing primer sold through a mail order catalog.

Packaging for MAA-containing nail primers that is senior friendly ("SF") and CR is technically feasible. There are currently available 20 mm CT caps without built-in applicator brushes that are SF and CR. The manufacturer of this cap also manufactures a 28 mm CT closure that is CR and SF and has a built in applicator brush. This manufacturer has indicated to staff that it could develop a 20 mm CR and SF cap with a built-in applicator brush suitable for use with MAA within 6 months to a year. Manufacturers of bottles with smaller finishes (the part of a bottle that receives the cap) may have to change to bottles with 20 mm finishes. However, this should not present a problem since some of the smallest sizes of bottles used for MAA-containing primers (0.25 ounces) already have a 20 mm finish. Manufacturers of MAA-containing primers concerned with spillage have the additional option of using a variety of commercially available restrictive inserts to decrease the inside diameter of the bottle opening in conjunction with CR 20 mm finishes. One manufacturer of MAA-containing primers currently uses such a restriction.

Special packaging for MAA-containing household products is practicable. CT caps that meet the senior friendly and CR testing requirements have been in mass production for many years. A 20 mm continuous threaded closure that is CR and SF but lacks an insert for a brush is now in mass production. Similarly, a 28 mm continuous threaded closure that is CR and SF and does have an insert for a brush is in mass production. The mass production and assembly line techniques used for the 28 mm CR and SF closure with insert can be adapted to those used for the 20 mm non-CR closure with an insert and brush.

Special packaging is appropriate when it will protect the integrity of the substance and not interfere with intended storage or use. Nail primers containing MAA are currently packaged in both glass and plastic bottles. Thus, both glass and plastic containers are suitable for MAA-containing products. One packaging manufacturer uses identical materials to produce a 28 mm continuous threaded CR and SF closure (equipped with an insert for attaching a brush) and a 20 mm continuous threaded non-CR closure that is currently used for MAA-containing primers and is equipped with an insert and attached brush. Plastic bottle neck restriction devices should also be compatible with MAA since at least one is already in use. Therefore, the same materials used for non-CR packages of MAA-containing products, with or without brushes or inserts, are used or can be used for CR-packages.

3. Other Considerations

In establishing a special packaging standard under the PPPA, the Commission must consider the following:

a. The reasonableness of the standard;

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

c. The manufacturing practices of industries affected by the PPPA; and

d. The nature and use of the household substance. 15 U.S.C. 1472(b).

The Commission has considered these factors with respect to the various determinations made in this notice, and preliminarily finds no reason to conclude that the rule is unreasonable or otherwise inappropriate.

F. Exemption

The Commission is aware of one MAA-containing primer that is packaged in a tube with a fiber applicator tip. The container looks like a plastic marker pen. The fiber strand holds the MAA so that no free liquid flows through the device. An overcap covers the applicator tip. Several manufacturers market this type of device for applying nail primer. Some of these primers contain MAA.

The Commission believes that MAA-containing primers packaged in this type of device do not pose a risk of serious injury. For this type of package not to pose a risk to children, the Commission believes that two conditions must be met: (1) the absorbent material must hold the MAA so that no free liquid is in the device, and (2) through reasonably foreseeable use the MAA will be released only through the tip of the device. Reasonably foreseeable use would include reasonably foreseeable abuse by children. These conditions are grounded in an existing exemption from FHSA labeling for porous-tip ink-marking devices. 16 CFR 1500.83(a)(9).

Although it might be possible to develop a lug finish CR closure to overcap these devices, based on the design of these devices and available injury information, the Commission

does not believe that a CR cap is necessary. The volume of MAA available and accessible is extremely small (total amount of material in the devices is reportedly less than 1/2 gram). The only possible route of serious injury would be from direct contact of the felt tip with the eye. The staff has not identified any incidents involving these types of devices. Thus, the Commission proposes to exempt MAA containing primers contained in these marker-like devices if they meet the conditions discussed above.

G. Effective Date

The PPPA provides that no regulation shall take effect sooner than 180 days or later than one year from the date such final regulation is issued, except that, for good cause, the Commission may establish an earlier effective date if it determines an earlier date to be in the public interest. 15 U.S.C. 1471n.

The Commission proposes a one year effective date. Currently, 20 mm CT caps that are CR and senior friendly are available. However, these caps are not available with a built-in applicator brush. Thus, manufacturers will need to make some modifications to provide a CR cap with a built-in applicator. Such closures should be available within one year. This includes time for closure manufacturers to produce the 20 mm closures and for product manufacturers to change existing assembly lines to accommodate these closures. Some manufacturers may need to change the bottles currently in use to bottles with 20 mm finishes. A year provides time to produce commercial quantities of the 20 mm CR and SF closures, adjust assembly lines to a different bottle size, and conduct testing following the PPPA protocol.

Thus, the Commission proposes that a rule would take effect 12 months after publication of a final rule and would apply to products that are packaged on or after the effective date.

H. Regulatory Flexibility Act Certification

When an agency undertakes a rulemaking proceeding, the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, generally requires the agency to prepare proposed and final regulatory flexibility analyses describing the impact of the rule on small businesses and other small entities. Section 605 of the Act provides that an agency is not required to prepare a regulatory flexibility analysis if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The Commission's Directorate for Economic Analysis prepared a preliminary assessment of the impact of a rule to require special packaging for household products containing more than 5 percent methacrylic acid.

As noted above, the Commission is aware of 13 companies that market nail primers containing MAA. Seven of these may be small businesses. As discussed above, the technology exists to produce CR packaging suitable for use with MAA-containing nail primers. Requiring special packaging for these nail primers may affect many small suppliers. However, the impact on any individual supplier is expected to be small. Generally, incremental costs for CR packaging are low relative to the retail cost of the product. Moreover, these incremental costs would likely be passed on to users (professional nail technicians and consumers who purchase these nail primers). Thus, based on current information, the Commission certifies that the proposed rule is not likely to have a substantial effect on a significant number of small businesses. The Commission requests suppliers, particularly small businesses, to provide information on the impact the proposed rule would have on them.

I. Environmental Considerations

Pursuant to the National Environmental Policy Act, and in accordance with the Council on Environmental Quality regulations and CPSC procedures for environmental review, the Commission has assessed the possible environmental effects associated with the proposed PPPA requirements for MAA-containing products.

The Commission's regulations state that rules requiring special packaging for consumer products normally have little or no potential for affecting the human environment. 16 CFR 1021.5(c)(3). Nothing in this proposed rule alters that expectation. Therefore, because the rule would have no adverse effect on the environment, neither an environmental assessment nor an environmental impact statement is required.

J. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations.

The PPPA provides that, generally, when a special packaging standard issued under the PPPA is in effect, "no State or political subdivision thereof shall have any authority either to establish or continue in effect, with respect to such household substance, any standard for special packaging (and any exemption therefrom and requirement related thereto) which is not identical to the [PPPA] standard." 15 U.S.C. 1476(a). Upon application to the Commission, a State or local standard may be excepted from this preemptive effect if the State or local standard (1) provides a higher degree of protection from the risk of injury or illness than the PPPA standard and (2) does not unduly burden interstate commerce. In addition, the Federal government, or a State or local government, may establish and continue in effect a non-identical special packaging requirement that provides a higher degree of protection than the PPPA requirement for a household substance for the Federal, State or local government's own use. 15 U.S.C. 1476(b).

Thus, with the exceptions noted above, the proposed rule requiring CR packaging for household products containing more than 5 percent MAA would preempt non-identical state or local special packaging standards for such MAA containing products.

In accordance with Executive Order 12612 (October 26, 1987), the Commission certifies that the proposed rule does not have sufficient implications for federalism to warrant a Federalism Assessment.

List of Subjects in 16 CFR Part 1700

Consumer protection, Cosmetics, Infants and children, Packaging and containers, Poison prevention, Toxic substances.

For the reasons given above, the Commission proposes to amend 16 CFR part 1700 as follows:

PART 1700—[AMENDED]

1. The authority citation for part 1700 continues to read as follows:

Authority: Pub. L. 91–601, secs. 1–9, 84 Stat. 1670–74, 15 U.S.C. 1471–76. Secs 1700.1 and 1700.14 also issued under Pub. L. 92–573, sec. 30(a), 88 Stat. 1231. 15 U.S.C. 2079(a).

2. Section 1700.14 is amended by republishing the introductory text of paragraph (a) and adding new paragraph (a)(29) to read as follows:

§ 1700.14 Substances requiring special packaging.

(a) Substances. The Commission has determined that the degree or nature of the hazard to children in the availability of the following substances, by reason of their packaging, is such that special packaging meeting the requirements of § 1700.20(a) is required to protect children from serious personal injury or

serious illness resulting from handling, using, or ingesting such substances, and the special packaging herein required is technically feasible, practicable, and appropriate for these substances:

* * * * *

(29) Methacrylic acid. Except as provided in the following sentence, liquid household products containing more than 5 percent methacrylic acid (weight-to-volume) in a single retail package shall be packaged in accordance with the provisions of § 1700.15(a),(b) and (c). Methacrylic acid products applied by an absorbent material contained inside a dispenser (such as a pen-like marker) are exempt from this requirement provided that: the methacrylic acid is contained by the absorbent material so that no free liquid is within the device; and under any reasonably foreseeable conditions of use the methacrylic acid will emerge only through the tip of the device.

* * * * *

Dated: December 21, 1998.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

List of Relevant Documents

1. Briefing memorandum from Susan Aitken, Ph.D., EH, to the Commission, "Proposed Special Packaging Standard for Household Products Containing Methacrylic Acid," November 23, 1998.
2. Memorandum from Susan Aitken, Ph.D., EH, to Mary Ann Danello, Ph.D., Associate Executive Director, EH, "Toxicity of Methacrylic Acid" August 12, 1998.
3. Memorandum from Susan C. Aitken, Ph.D., EH, to Mary Ann Danello, Ph.D., EH, "Human Injuries from Nail Products Containing Methacrylic Acid," August 12, 1998.
4. Memorandum from Marcia P. Robins, EC, to Susan Aitken, Ph.D., EH, "Economic Considerations: Proposal to Require Child-Resistant Packaging for Household Products Containing Methacrylic Acid," August 17, 1998.
5. Memorandum from Tewabe A. Asebe, EH, to Susan Aitken, Ph.D., EH, "Technical Feasibility, Practicability, and Appropriateness Determination for Proposed Rule to Require Special Packaging for Methacrylic Acid-Containing Products," August 17, 1998.
6. Memorandum from Bhooshan Bharat, Ph.D., LS, and Bhavi K. Jain, MS, LS, "Report on the Testing of Nail Products for Titratable Acid Reserve ("TAR"), Quantification of Methacrylic Acid, and pH," August 20, 1998.

[FR Doc. 98-34345 Filed 12-29-98; 8:45 am]

BILLING CODE 6355-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 161, 250, and 284

[Docket Nos. RM98-10-000 and RM98-12-000]

Regulation of Short-Term Natural Gas Transportation Services; Regulation of Interstate Natural Gas Transportation Services; Order Granting Extention of Time for Filing Comments

December 23, 1998.

AGENCY: Federal Energy Regulatory Commission, DOE

ACTION: Order granting extension of time for filing comments.

SUMMARY: On July 29, 1998, the Commission issued a Notice of Proposed Rulemaking (NOPR) in Docket No. RM98-10-000 (63 FR 42982) and a Notice of Inquiry (NOI) in Docket No. RM98-12-000 (63 FR 42974) dealing with the Regulation of Short-Term Natural Gas Transportation Services. The date for filing comments in these proceedings is being extended at the request of various interested parties.

DATES:

Comments on the NOPR are extended to and including April 22, 1998.

Comments on the NOI are extended to and including February 22, 1998.

ADDRESSES: Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426.

FOR FURTHER INFORMATION CONTACT: David P. Boergers, Secretary 888 First Street, N.E., Washington, D.C. 20426, (202) 208-0400.

Before Commissioners: James J. Hoecker, Chairman; Vicky A. Bailey, William L. Massey, Linda Breathitt, and Curt Hébert, Jr.

Regulation of Short-Term Natural Gas Transportation Services, Docket No. RM98-10-000

Regulation of Interstate Natural Gas Transportation Services, Docket No. RM98-12-000

Order Granting Extension of Time for Filing Comments

(Issued December 23, 1998)

On December 7, 1998, the Natural Gas Council (composed of the American Gas Association, the Interstate Natural Gas Association of America, the Natural Gas Supply Association, and the Independent Petroleum Association of America) joined by the Process Gas Consumers Group, the American Iron and Steel Institute, the Georgia Industrial Group, and the Edison Electric Institute submitted a letter, filed in Docket No. RM98-10-000, requesting an extension of time until April 22, 1999, within which to file comments in response to the Commission's Notice of Proposed Rulemaking (NOPR), issued July 29, 1998, in Docket No. RM98-10-000,[1] and the Notice of Inquiry (NOI), issued July 29, 1998, in Docket No. RM98-12-000.[2] Comments on the NOPR and NOI currently are due by January 22, 1999.

The Commission will grant an extension, until April 22, 1999, for parties to file comments on the NOPR and NOI. However, the Commission would be interested in any comments that can be filed on a voluntary basis, within the current schedule addressing the relationship between the short-term issues in the NOPR and the long-term issues in the NOI. The Commission emphasizes that any comments filed in January will not be the last opportunity for parties to have input on these important matters. The Commission merely wishes to be more fully apprised of the current state of the parties' ideas.

So far, the public discussions on the proposals in the NOPR and NOI have concentrated on the issue of auctions. The other issues included in the NOPR, such as negotiated terms and conditions or certificate policy, have received little attention. Similarly, there has been little dialogue concerning rate designs for long-term contracts that would remove or lessen the current bias toward short-term contracts. The extension will provide time for the industry to focus on these important issues and to better formulate comments. The informal dialogue that has occurred to date between the Commission staff and all the segments of the industry appears to have been worthwhile. The extension also will give the Commission's staff the opportunity to continue holding conferences and using other means to continue the interaction with all segments of the industry on all of the issues raised in the NOPR and NOI. The Commission requests that by January 22, 1999, parties identify any issues, other than those related to auctions, for which it might be beneficial for the Commission staff to convene a technical conference during the pendency of the extended comment period.

The additional time has been requested to permit the groups who joined in the request to engage in further discussions regarding the issues raised in the NOPR and NOI. The results of such consensus-building efforts will be of most value to the Commission if they

[1] 63 FR 42982 (Aug. 11 1998).

[2] 63 FR 42974 (Aug. 11 1998).

TAB B

United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: 3/15/99

TO : EHHS

Through: Sadye E. Dunn, Secretary, OS

FROM : Martha A. Kosh, OS

SUBJECT: Requirements for Child-Resistant Packaging; Household Products Containing Methacrylic Acid

ATTACHED ARE COMMENTS ON THE CP99-1

COMMENT	DATE	SIGNED BY	AFFILIATION
CP99-1-1	1/25/99	Ila Hirsch	Beatrice Kaye 12970 San Vicente Blvd Los Angeles, CA 90049
CP99-1-2	2/10/99	Larry Gaertner	No Lift Nails, Inc. 5301 Business Dr. Huntington Beach, CA 92649
CP99-1-3	3/11/99	Joel Alpert MD, FAAP President	American Academy of Pediactrics The Homer Building 601 Thirteenth St, NW Suite 400 North Washington, DC 20005
CP99-1-4	3/15/99	William Althen Atty On behalf of American Beauty Association	Heenan, Althen & Roles Suite 400 1110 Vermont Ave, NW Washington, Dc 20005
CP99-1-5	3/17/99	Elizabeth Hunt Exe Director	Methacrylate Producers Association, Inc. 1250 Connecticut Ave, NW Suite 700 Washington, DC 20036

CP99-1-1

Beatrice Kaye

January 25, 1999

Susan C. Aitken, Ph.D.
Pharmacologist
Division of Health Sciences
U.S. CPSC
4330 East-West Highway
Bethesda, MD 20814

RE: 16CFR Part 1700

Dear Dr. Susan Aitken,

While I appreciate being on the list to be notified about upcoming safety packaging for Methacrylic Acid, I feel that the bigger issue is alerting unsuspecting manicurists and citizenry about the potential harm of using this chemical in the beauty field.

The unfortunate examples of health problems as a result of coming in contact with the substance are all of the accidental nature. The real problem is that an entire industry of salon professionals and patrons are exposing themselves to the substance and vapors of this substance and their slightly altered relative substances without the least bit of forewarning. There is no way of safely testing the results on lungs, female organs and unborn fetuses.

I am constantly requesting that our State Cosmetology Board take some action to alert students in cosmetoloy schools and salon patrons. As we all know, large cosmetic companies just stay one step ahead of the changes and pose health threats with altered chemicals.

Please see that my comments are entered into public record.

Thank you,

Ila M. Hirsch

IMH/RSC

encl.

12970 San Vicente Boulevard ★ Los Angeles, California 90049
310 394-3277 ★ FAX 310 451-4469

HIRSCH

1370 SAN VICENTE BLVD
LOS ANGELES CA 900[illegible]

Telephone 310 [illegible]
Fax 310 [illegible]

January 9, 1999

Pamela Reed
Program Administrator
Barbering and Cosmetology Program
P.O. Box 944226
Sacramento, CA 94244

RE: Advisory Council Curriculum Task Force-Schools

Dear Pamela Reed,

I wish you and all of the State Board and Advisory Council Members a happy and healthy New Year as we get around to addressing the serious matter of the instruction of those students that look to our Barbering and Cosmetology Programs to give them the necessary information to lead a productive and healthy life in the services that they choose to perform for the general public.

The time has come to make important decisions about our school instruction policies. The State Board must assume the responsibility of alerting the unsuspecting student, instructor and patron that products that they are using can be harmful to health. I suggest that a simple form be required of all those that begin instruction and that a notice be placed on the entrance of any establishment that uses chemicals that can be harmful to health.

Secondly, I suggest that the time has come to establish an educational program for cosmetologists that can provide the education for the professional without using products that can be harmful for health.

The Barbering and Cosmetology Program will be held accountable for not disseminating this information. The chemical content and hazards to health of the products used in the beauty profession must be identified and acknowledged.

I request that this letter be included in the public record for the Meeting of the Curriculum Task Force by the manicurist member and if she is not present, as per last meetings, I request to be named as the substitite or alternative.

The actions that we take at this first meeting of the new year will help generations.

Sincerely,

Ila Hirsch

Ila M. Hirsch
IMH/RSC

cc: Governor Gray Davis
FDA

Consumer Affairs

BARBERING AND COSMETOLOGY PROGRAM
P.O. BOX 944226
SACRAMENTO, CA 94244-2260
INFORMATION: (916) 327-6250 FAX (916) 445-8893

July 28, 1998

Ms. Ila Hirsch, President
Beatrice Kaye
12970 San Vicente Boulevard
Los Angeles, CA 90049

Dear Ms. Hirsch:

Thank you for your letter dated June 23, 1998. This letter was provided to all Advisory Council members at the July 27, 1998 meeting in San Diego.

While air quality in licensed establishments is a concern to the Barbering and Cosmetology Program it is not within the purview of our mandate. As previously stated, if this issue is to be addressed you must contact the appropriate State agency for assistance.

The mission of the Barbering and Cosmetology Program (B&CP) is to protect the public welfare by licensing only qualified persons, establishing and enforcing appropriate standards of competency and practice and educating consumers to enable them to make informed decisions in the market place. To this end, it is encumbent upon the B&CP to identify those products and/or services that may cause potential harm to the consumer, identify the health and safety concerns associated with them and examine potential candidates for licensure on the knowledge, skills and abilities associated with these health and safety concerns for the protection of the consumer. While you may not agree with the testing of candidates on the use of chemical products associated with this industry, from a consumer protection vantage point, the B&CP would be remiss in its responsibilities if this were eliminated.

Additionally, the B&CP does not have jurisdiction over the issue of air quality in its licensed establishments. Therefore, we do not have the authority to pursue this issue. In my previous letter I provided you with referrals to the Division of Occupational Safety and Health and the California Building Standards Commission. The Advisory Council members have additionally suggested you contact the Air Resources Control Board. You may contact them at 2020 L Street, P.O. Box 2815, Sacramento, CA 95812 to determine if they can assist you.

If I can be of assistance in the future please do not hesitate to contact me at the letterhead address noted above.

Sincerely,

Pamela Reed
Program Administrator

PR/sv
cc Members, Advisory Council

Beatrice Kaye

May 18, 1998

Pamela Reed
Program Administrator
Barbering and Cosmetology Program
P.O. Box 944226
Sacramento, CA 94244-2260

RE: Advisory Council Meeting/Salon Sanitation

Dear Miss Pamela Reed and Advisory Council Meeting

Both consumers and professionals are currently at risk due to health practices that are not being addressed. Artificial nails fumes that are present in salons are harmful. This is a much more important issue than the amount of hair on a floor.

Salon ownership and booth rental questions are just obfuscating the fact that "olfactory assault" is taking place every minute that consumers and professionals are in salons that are contaminated. Inadequate ventilation requirements and limited formulation changes cannot diminish risks.

The time for a serious discussion about the air quality problem that exits in beauty salons and nail salons is at hand. Unsuspecting consumers and professionals deserve to have their health taken more seriously.

I propose that the Advisory Council study the health problems of our professionals. I also would like to open debate on the reduction of salon pollution and the establishment of a designation for shops and salons that can be identified as clean air salons. I am also suggesting that it is time the licensing of professionals is more in line with the health and beauty.

I look forward to taking part in discussions regarding the above topics.

Sincerely,

Ila M. Hirsch
President

IMH/RSC

cc: Pete Wilson, Governor
David Satcher, Assistant Secretary For Health

12970 San Vicente Boulevard ★ Los Angeles, California 90049
310 394-3277 ★ FAX 310 451-4469

Beatrice Kaye

September 16, 1998

Roger L. Mayer
President
Turner Entertainment Co.
1888 Century Park East 14th Floor
Los Angeles, CA 90067

Re: Beatrice Kaye Humanitarian Efforts

Dear Mr. Mayer,

Beatrice and I would very much like to thank you for your sincere and honest concern for both our company and our causes.

The Beatrice Kaye Company has always represented the highest quality of beauty care and products. Our "world renown company" is a classic just like the original MGM Studio films and particularly, "Gone With The Wind." Beatrice Kaye's natural nail manicuring products and techniques have brought beauty and health to many people and saved countless individuals from painful arthritic conditions.

Our company would very much appreciate any support in trying to save the lungs, organs and unborn fetuses of those that unsuspectingly use artificial nails in the pursuit of beautiful hands. Second hand cigarette smoke was a new concept a short time ago. Acrylic nails are harmful chemicals. We could never have sold out the health of future generations for present monetary gain. However, the time has come to ask for help in our efforts to inform the public about healthy hand hygiene. It is like David fighting Goliath.

Thank you again for any help in the area of recognition or publicity.

Sincerely,

Ila M. Hirsch.

IMH/RSC

encl.

cc: Senator Rick Santorum

12970 San Vicente Boulevard ★ Los Angeles, California 90049
310 394-3277 ★ FAX 310 451-4469

CP99-1-2

No Lift Nails®

NO LIFT NAILS, INC. • (714) 897-0070 • (800) 779-6245 • FAX (714) 897-0409 • noliftnail@aol.com

2/10/99

To whom to it may concern,

The problem with child resistant caps, is that there are no caps available that will fit a 15 mm neck.
The 15 mm neck is important in that it does not allow the primer to spill all over the table when the bottle is tipped.
I sincerely feel that the majority of child injury cases were caused from parental neglect. Hopefully by placing child resistant caps on nail primer, this will not increase the sale of primer into the home, however, if they save one child from injury, it will be worth it.
It is our wish, that with the caps in place on the few primers taken into the households with small children that they will make a difference.
Now that we may have to go to a 20 mm neck in order to comply with your rule requiring child resistant caps, my concern , is with the manicurists that uses the primer everyday to make a living. When they are working with the primer, most professionals leave the cap off the bottle.
We respectfully recommend that you try and make it safer for them, by requiring that the primer sold, have a small orifice, so that when the bottle is spilled the primer will not run all over the table and onto there lap. We also recommend that primer not be sold in a bottle larger than 1/2 oz.
In twenty years of selling primer we have come to the conclusion that the 1/2 oz. bottle and the small orifice has saved many professional manicurists from the discomfort of a primer burn.
I know that when the rule goes into effect some companies will put their primer into a 1 oz. container with a 20 mm neck and sell it .
They may as well sell a loaded gun, because as sure as tomorrow, we will be having this same discussion, two or three years from now, about protecting adults from spillage.
Let's do it right this time around, since we will have child resistant caps, then can't you help us make it safe for the professional as well?

Sincerely ,

Larry Gaertner
No Lift Nails Inc.

CP99-1-3

American Academy of Pediatrics

Reply To:
Department of Federal Affairs
American Academy of Pediatrics
The Homer Building
601 Thirteenth Street, NW
Suite 400 North
Washington, DC 20005
202/347-8600
800/336-5475
Fax: 202/393-6137
e-mail: kids1st@aap.org
http://www.aap.org

March 11, 1999

Office of the Secretary
Consumer Product Safety Commission
4330 East-West Highway
Room 502
Bethesda, MD 20814-4408

RE: Proposed Rule on Requirements for Child-Resistant Packaging; Household Products Containing Methacrylic Acid (16 CFR Part 1700)

To Whom It May Concern:

On behalf of the American Academy of Pediatrics, I offer our support for the proposed rule requiring child-resistant packaging of household products containing more than five percent of methacrylic acid.

The American Academy of Pediatrics is an organization of 55,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

Methacrylic acid is commonly found in nail care products, specifically in the primers used to adhere acrylic nails to the natural nail surface. Its corrosive nature is capable of causing permanent disability or death. Children who are exposed face possible skin burn, oral and esophageal burns, nasal irritation and blindness. A significant complication following ingestion of methacrylic acid is esophageal stricture, which may produce lifelong swallowing difficulties and a risk for cancer of the esophagus. Between 1993 and 1995, methacrylic acid found in nail care products were the cause of 759 reports of exposure to poison control centers – with more than 74 percent occurring in children less than 6 years-old.

Because of the potential harm posed to children exposed to methacrylic acid and its common use in the home for nail care, the American Academy of Pediatrics supports the proposed rule requiring child-resistant packaging.

Sincerely,

Joel J Alpert, MD

Joel J. Alpert, MD, FAAP
President

JJA/kbf

CPSC-1-4

AMERICAN BEAUTY ASSOCIATION

Comment Regarding Proposed Rule Requiring Child-Resistant Packaging; Household Products Containing Methacrylic Acid

63 Fed. Reg. 71800 (December 30, 1998)

The American Beauty Association ("ABA") is a non-profit, trade association representing over 200 manufacturers of professional-use salon products and over eighty percent (80%) of products sold in the professional salon industry. As the association representing manufacturers of products used in professional salons applications, ABA ordinarily does not comment upon matters involving consumer and/or household cosmetic products. However, ABA believes that every manufacturer of cosmetics and every association in the professional and consumer cosmetics industries must be concerned with preventing hazards to children that may result from any product.

ABA's and its members' commitment to safety is demonstrated by a long record of active participation in, and encouragement of, industry-wide safety programs. ABA expects compliance by all members with government safety requirements and programs and strongly encourages all companies to participate in voluntary programs directed toward cosmetic safety.

While ABA strongly affirms the need for, and efficacy of, voluntary industry actions supporting and preserving the safety of all products, ABA also supports reasonable and appropriate rules by federal and state agencies designed to assure the safety of products. Rules are useful and efficacious when promulgated within an agency's area of jurisdiction after full and fair consideration of all relevant data, including safety, scientific, feasibility, cost and other information bearing upon the need for the rule and the reasonableness of a particular proposal.

ABA finds that the Consumer Product Safety Commission has engaged in such a full and fair analysis in the proposed rule related to household products containing methacrylic acid. ABA submits that the Commission fairly weighed the hazards to children from household products containing methacrylic acid and properly considered those hazards in conjunction with a fair analysis of the practicality and feasibility of protecting children against the hazards. As a result, ABA supports the proposed rule related to household products and suggests adoption of the rule in the form proposed by the Commission.

METHACRYLATE PRODUCERS ASSOCIATION, INC.

1250 Connecticut Avenue, N.W., Suite 700, Washington, D.C. 20036
Office: (202) 637-9040 Facsimile: (202) 637-9178

March 17, 1999

VIA U.S. MAIL

Sadye E. Dunn
Office of the Secretary
Consumer Product Safety Commission
Washington, D.C. 20207

Re: Child-Resistant Packaging for Household Products Containing Methacrylic Acid

Dear Ms. Dunn:

The Methacrylate Producers Association, Inc. (MPA) supports CPSC's proposal to require child-resistant packaging for liquid household products containing more than 5 percent methacrylic acid (MAA).

MPA is an association of manufacturers of methacrylic acid and methacrylates, whose members include ICI Acrylics, Inc., CYRO Industries, Elf Atochem N.A., Inc., and Rohm and Haas Company. MPA and its members have product stewardship programs to promote appropriate use of the chemicals they market. MPA members have for many years recommended that methacrylic acid and its esters in their unreacted monomeric liquid form not be used in cosmetics. The known corrosive properties of the acid and the skin sensitization properties of the esters, as underscored by recent reports of injury due to their use in some nail products, indicates that their use in cosmetics should be restricted. If that use is to continue, it is certainly appropriate for CPSC to require that any such products be in child-resistant packaging.

MPA recently asked the Cosmetics Ingredient Review to review use of methacrylic acid and its basic esters in their unreacted liquid form in cosmetics including nail products and to find that such use is inappropriate. MPA has also provided information to the Food and Drug Administration and has previously sent to CPSC background toxicity information on MAA and methacrylates, including a skin irritation study of methacrylic acid in rabbits (Rohm and Haas 1997) that found evidence of corrosivity with exposures as short as three minutes.

As the CPSC notes, the hazards posed by use of unreacted methacrylic acid in nail products was highlighted in Dr. Woolf's January 1998 article in the Archives of Pediatric and Adolescent Medicine, which collected from the Toxic Exposure Surveillance System reports of severe burns in children due to exposure to artificial nail primers whose primary ingredient was methacrylic acid. Dr. Woolf found the artificial fingernail primers were not polymers, but rather greater than 70% free methacrylic acid. As the article noted, some of these products may be intended for purchase by professional beauticians; but they are also widely available to, and used by, the consuming public given the current trend in artificial fingernail application toward more home application (of products intended for professional use). At home, where caveats against skin contact are much less likely to be heeded, and accidental exposures of children have occurred, the need for child-resistant packaging is clear.

MPA thus urges CPSC to adopt its proposed child resistant packaging proposal for household products containing MAA.

Sincerely yours,

Elizabeth K. Hunt

Elizabeth K. Hunt
Executive Director

cc: Susan Aitken, Ph.D.
Division of Health Sciences

TAB C

United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: 08 APR 1999

TO : Susan C. Aitken, Ph.D., Project Manager
Methacrylic Acid

Through: Warren J. Prunella, AED, EC *wjp*

FROM : Marcia P. Robins, *mpr* EC

SUBJECT: Final Rule for Child-Resistant Packaging for Household Products Containing Methacrylic Acid: Regulatory Flexibility Issues

The Regulatory Flexibility Act (RFA [PL 96-345]) generally requires agencies to prepare and make available for public comment an initial regulatory flexibility analysis describing the impact of the rule on small businesses and other small entities, when a general notice of proposed rulemaking is published in the *Federal Register* (FR). However, under section 605, no such analysis is required if the Commission certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

On December 30, 1998, CPSC published a Notice of Proposed Rulemaking (NPR) to require child-resistant (CR) packaging for household products containing methacrylic acid. In this notice, the Commission concluded that the proposal would not have a significant economic effect on a substantial number of small businesses or other small entities. The determination was based on the following information.

Methacrylic acid is primarily found in primers for nail enhancement procedures involving acrylic nail overlays. Although these products are typically labeled *For Professional Use Only*, they can be purchased by the general public. A requirement that methacrylic acid-containing products meet Poison Prevention Packaging Act (PPPA) standards will affect all suppliers. Industry sources estimate the number of suppliers at 20 to 50; almost all are small businesses.

The Nail Manufacturers Council (NMC) of the American Beauty Association (ABA) represents suppliers of professional nail preparations. At a meeting with CPSC staff in April 1998,

representatives of the NMC commented that the member companies were considering the voluntary use of CR packaging for nail primers containing methacrylic acid but had not found a packaging supplier.

In the December 1998 FR notice, information was provided on currently available and potentially available CR packaging for nail primers. Staff noted that CR closures without built-in applicator brushes are currently available, and that at least one manufacturer indicated that it could develop a CR closure with a built-in applicator brush suitable for methacrylic acid-containing primers. Staff also noted that primers packaged in a tube with a fiber applicator tip do not pose a risk of serious injury to young children and proposed to exempt primers contained in marker-like devices if they meet specified conditions.

Public comments on the proposal were supportive of a CR requirement. In a follow-up telephone call to one commenter, staff was told the company is already phasing in a fiber applicator tip package that would be exempt from CR requirements. A second commenter reports finding an acceptable commercially produced CR package for the company's primer. In addition, staff has been advised that some manufacturers are forming a consortium to fund the development of new molds for CR closures for nail primers.

Since CR packaging is readily available at low incremental costs, the costs will not have a significant economic impact on small businesses marketing methacrylic acid-containing products. Nor should the CR packaging requirement for methacrylic acid-containing products be an entry barrier for future small business marketers. Moreover, there are no recordkeeping or reporting requirements under the PPPA.

The public comments on the proposed rule support the proposal and provided no information regarding potential adverse impacts on small businesses or other small entities. Based on all of the economic information available on the proposed rule, the Directorate for Economic Analysis concludes that the final action to require CR packaging for household products containing more than 5 percent methacrylic acid in a single package will not have a significant economic effect on a substantial number of small entities.

TAB D

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: April 23, 1999

TO: Susan C. Aitken, Ph.D., Project Manager, Methacrylic Acid, Division of Health Sciences

Through: Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Epidemiology and Health Sciences MAD

Lori E. Saltzman, M.S., Director, Division of Health Sciences, Directorate for Epidemiology and Health Sciences

FROM: Tewabe Asebe, Industrial Engineer, CPP, Division of Health Sciences T. A.

SUBJECT: Assessment of Technical Feasibility, Practicability, and Appropriateness for the Final Rule to Require Child-Resistant (CR) Packaging for Products Containing 5 percent (weight/volume) Methacrylic Acid.

No technical feasibility, practicability, and appropriateness comments were received since the proposed rulemaking was published to require special packaging for products containing 5 percent or more (weight/volume) methacrylic acid (Federal Register, Volume 63, No. 250).

The U.S. Consumer Product Safety Commission (CPSC or Commission) can issue requirements that certain household substances be sold in "special packaging" or child-resistant (CR) packaging under the Poison Prevention Packaging Act (PPPA or the Act) of 1970. To require CR packaging for products containing more than 5 percent (weight/volume) methacrylic acid, the Commission needs to make the finding that CR packaging is technically feasible, practicable, and appropriate for these products (15 U.S.C. 1472 (a)(2) Sec. 3).

TECHNICAL FEASIBILITY

Technical feasibility exists when technology is available or can be readily developed to produce packaging that conforms to the standards.

Ten nail primer products were previously evaluated by the staff. All of these products are currently packaged in non-child-resistant (NCR) packaging.[1] Laboratory tests conducted by the CPSC Laboratory Sciences, Division of Chemistry (LSC) confirmed that five out of ten samples contained methacrylic acid. The methacrylic acid-containing products were packaged in 0.25 to 2 ounce (oz) bottles with 13 to 20 millimeter (mm) non-child-resistant-continuous-threaded (NCRCT) plastic closures (a continuous threaded package has matching spiral ridges on both the inside of a cap and the outside neck of the corresponding bottle). Four of the five bottles were made of glass and the fifth one was made of plastic material.

Three products were packaged with a built-in applicator brush attached at the inside center of their NCRCT caps. One product was packaged with a separately provided applicator brush, and one had no applicator brush.

In addition to the five products, one other product that contains methacrylic acid was evaluated recently.[12] This product is packaged in a plastic marker type packaging.[8] The package looks like a pen with a marker type tip (moistened fiber applicator tip)*. The applicator tip is overcapped with a NCR overcap. Child protocol test data for an ASTM Type IIA (lug finish), 16 mm outer diameter package suggests that it may be redesigned and used for the plastic marker type packaging.[11] The descriptions of these six package types are summarized in Table 1.

Table 1. Descriptions of Packages with Methacrylic Acid-containing Products.

Cap					Bottle			
Size (mm)	Type	Material	Long Skirt (mm)	Applicator Brush	Size (Oz.)	Color	Material	Coating
20	NCRCT	plastic	No	built-in	2	clear brown	glass	No
20	NCRCT	plastic	No	built-in	0.25	clear brown	glass	No
15	NCRCT	plastic	27	separate	0.5	clear	glass	black
13	NCRCT	plastic	27	built-in	0.25	clear	plastic	black
13	NCRCT	plastic	No	No	0.5	clear	glass	purple
10	NCR-SNAP	plastic	N/A	marker tip	0.07 (2 g)	white	plastic	No

* Under specific existing conditions, the staff recommends that the Commission exempt this package design for methacrylic acid-containing products from a requirement for CR packaging.

On April 24, 1998, the staff met with the American Beauty Association and other nail care product manufacturers at the CPSC Headquarters. In response to questions about their use of small diameter finish (that part of a glass or plastic bottle that will receive the cap) glass bottles for some of their products, and the reasons for using a built-in applicator brush, the manufacturers responded that they use very small finish bottles mainly to prevent spillage of product. They also indicated that they provide a built-in applicator brush because they are concerned with spillage of the product while left opened for use. They added that the tendency to put the cap back on the bottle after product use may be less with a separately provided applicator brush than a built-in applicator brush. Also, the user may get injured by accidentally touching the applicator brush. They expressed interest in the development of CR (Note: CR implies also senior friendly) packaging for methacrylic acid-containing products.

One CR packaging manufacturer has a 28 mm CR ASTM[2] Type IA cap with a built-in inside insert for applicator brush.[3] The company also makes a 20 mm CR ASTM Type IA cap (without a built-in applicator brush insert) on a brown 1 oz glass bottle.[6] This manufacturer is also supplying 20 mm NCRCT packaging with a built-in applicator brush for methacrylic acid-containing products. The same manufacturer can produce a 20 mm CR ASTM Type IA package with a built-in applicator brush.[4] Another CR packaging manufacturer makes a CR cap with a 20 mm ASTM Type IA dropper.[5] Examination of the 28 mm CR cap and other existing packages suggests that this and other manufacturers could also develop 20 mm CR caps with built-in applicator brushes.

One European CR packaging manufacturer has a 9 mm, ASTM Type IA prototype cap developed for products packaged in tubes.[6] The cap may also be used with the same size finish bottles. The cap has a hole at its inside center that may be used to insert an applicator brush. At this time, staff do not have any protocol test data for this package and have no information when and if this package will be commercially developed for marketing in the United States.

The staff concludes that the available data support the finding that it is technically feasible to produce special packaging for methacrylic acid-containing products.

PRACTICABILITY

Practicability means that special packaging complying with the standards is adaptable to modern mass production and assembly line techniques.

The ASTM Type I caps have been in production for years and many of them meet PPPA protocol test standards.[3,5,7] Modern mass production and assembly line techniques used at the product filling line for existing NCRCT caps with built-in applicator brushes may also be used for the CR caps with built-in applicator brushes.[4,13] Most manufacturers are very small companies and they use manual filling lines.[13] Therefore, the CR packaging manual filling lines should not be any different from the NCR packaging filling lines.

At present, to the staff's knowledge, ASTM Type I packages only with 20 mm or higher finish exist in the market as CR packaging. Methacrylic acid-containing products packaged with less than a 20 mm finish may have to be changed to the 20 mm size packages. This should not be a problem since some of the smallest size products (0.25 oz. bottle, please see Table 1) are already packaged with 20 mm finish packages. If necessary, an insert can also be used to decrease the inside diameter of a bottle.[10] Manufacturers of methacrylic acid-containing products have the option of using commercially available restrictive insert designs to decrease the inside diameter of a bottle's opening. One manufacturer of a methacrylic acid- containing primer is currently using such a design to package its product in NCR packaging.

The manufacturer of a 28 mm CR ASTM Type IA cap with a built-in inside insert for applicator brush, can also produce the same cap in a 20 mm size. Once this 20 mm size CR cap is manufactured, it can be assembled on an adapted product filling line which already exists for the 20 mm NCRCT packages.[4] Therefore, information is available to support the findings that special packaging for methacrylic acid-containing products is practicable.

APPROPRIATENESS

Packaging is appropriate when it will adequately protect the integrity of the substance and not interfere with its intended storage or use.

Although most manufacturers use brown glass bottles, or plastic coated clear glass bottles with continuous-threaded (CT) finishes, one manufacturer uses a 0.25 oz clear, CT finish, plastic bottle with a black plastic coating. High density polyethylene (HDPE) packages with a CT finish can also be used for methacrylic acid-containing products.[9]

There are CRCT closures manufactured with materials that have identical properties to the existing NCRCT closures. Twenty mm sizes of these CRCT closures with built-in applicator inside inserts can be manufactured to replace the existing 20 mm NCRCT closures. The packaging manufacturer with the 28 mm, ASTM Type IA, CR cap with a built-in inside insert for applicator brush also manufactures 20 mm NCRCT caps with a built-in applicator brush for methacrylic acid-containing products. Both the CR and NCRCT caps are made from identical materials; the company can make a 20 mm CR cap with a built-in applicator brush with identical materials to the existing NCR packages. Data are, therefore, available to support the finding that special packaging for methacrylic acid-containing products is appropriate.

EFFECTIVE DATE

Section 8 of the PPPA specifies that the effective date shall not be sooner than 180 days or later than 1 year from the date the standard is promulgated in the Federal Register. Although

there is a 28 mm CR cap with a built-in inside insert for applicator brush on the market, the staff are not aware of a 20 mm finish CR package with a built-in applicator brush on the market for methacrylic acid-containing products. Also packages with less than 20 mm diameter finishes may have to be changed to 20 mm size packages to make them CR packaging. It would take about a year (tool design to production, protocol testing, to make changes at the production line, and to get enough supply for product manufacturers) for the packaging manufacturer to make 20 mm CR packaging with a built-in applicator brush for methacrylic acid-containing products. Therefore, an effective date of one year is recommended.

CONCLUSION

The staff concludes that data support the finding that special packaging for methacrylic acid-containing products is technically feasible, practicable, and appropriate. Twenty mm ASTM Type IA caps are available for packages with a separate applicator brush. These caps could also be developed with built-in applicator brushes. The packaging manufacturer with the 28 mm, ASTM Type IA, CR cap with a built-in inside insert for applicator brush also manufactures 20 mm NCRCT caps with built-in applicator brushes for methacrylic acid-containing products. Both the CR and NCRCT caps are made from identical materials and the company can make a 20 mm CR cap with a built-in applicator brush with identical materials to the existing NCR packages.

References

1. Asebe, T., Laboratory Report, Form 221, 13 mm to 20 mm NCRCT Closures on 0.25 FL. Oz. to 2 Oz. glass bottles, 98-594-0489, No. 3165 to 98-594-0494 No. 3170, 98-594-0496, No. 3173, and 98-594-0497, No. 3174, CPSC, EHHS, April 2, 1998.

2. ASTM, Standard Classification Child-Resistant Packages, D-3475, ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, Telephone 610-832-9739.

3. Asebe, T., Laboratory Report, Form 221, 28 mm, ASTM Type 1A Closure on a 40 cc, HDPE bottle, 96-400-0389, No. 2215, CPSC, EHPS, March 26, 1996.

4. Asebe, T., Personal Communication Memo, Major CR Packaging Manufacturer, Form 247, April 14, July 17, July 20, and July 22, 1998.

5. Asebe, T., Laboratory Report, Form 221, 20 mm, ASTM Type 1A Closure on a 15 cc, plastic, round, opaque bottle, 98-594-0503, No. 3175, CPSC, EHHS, April 16, 1998.

6. Asebe, T., Laboratory Report, Form 221, 9 mm, ASTM Type 1A, Reverse Ratchet Closure on a Metal Tube, 98-594-0553, No. 3243, CPSC, EHHS, May 21, 1998.

7. Asebe, T., Laboratory Report, Form 221, 20 mm, ASTM Type 1A Closure on a 1 Oz. oval, brown, glass bottle, 97-594-0427, No. 3093, CPSC, EHHS, December 9, 1996.

8. Asebe, T., Laboratory Report, Form 221, 10 mm OD NCR plastic marker type overcap on a 10 mm OD, 123 mm long plastic marker type applicator pen, 958-594-0515, No 3198. CPSC, EHHS, April 29, 1998.

9. PDL Handbook Series, Chemical Resistance, Volume I - Thermoplastics & Volume II - Thermosets and Rubbers, 2nd edition, Copyright © 1994, Plastics Design Library.

10. Asebe, T., Laboratory Report, Form 221, 24 mm, ASTM Type IA Closures on a 6 Fl. Oz.(177 ml), brown, oblong, HDPE bottle with internal neck plug insert, semi -opaque, plastic, dispensing hole (2 mm), 97-594-0292, No. 2929, CPSC, EHHS, June 9, 1997.

11. Asebe, T., Laboratory Report, Form 221, 16 mm, ASTM Type IIA Closures on an 18 mm top, 17 mm bottom diameters by 57 mm length conical, 4 lug, white tube, 97-830-3345, No. 2867, CPSC, EHHS, March 21, 1997.

12. Asebe, T., Laboratory Report, Form 221, NCR-Snap cap on a Pen with a white moistened fiber applicator tip, 99-590-0883, No. 3603, CPSC, EHHS, March 29, 1999.

13. Asebe, T., Meeting American Beauty Association, Form 247, April 24, 1998.

TAB E

[Billing Code 6355-01-P]

DRAFT 5/13/99

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Final Rule: Requirements for Child-Resistant Packaging; Household Products Containing Methacrylic Acid

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Commission is issuing a rule to require child-resistant ("CR") packaging for liquid household products containing more than 5 percent methacrylic acid (weight-to-volume) in a single package. The Commission has determined that child-resistant packaging is necessary to protect children under 5 years of age from serious personal injury and serious illness resulting from handling or ingesting a toxic amount of methacrylic acid. The Commission is specifically concerned about nail care products containing methacrylic acid, the only household product the Commission has confirmed contains methacrylic acid. The Commission takes this action under the Poison Prevention Packaging Act of 1970.

DATES: This rule will become effective on _____ [insert date that is 12 months after publication in the **FEDERAL REGISTER**] and applies to methacrylic acid preparations packaged on or after that date.

FOR FURTHER INFORMATION CONTACT: Laura E. W. Noble, Directorate for Compliance, U.S. Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504-0400 ext. 1452.

SUPPLEMENTARY INFORMATION:

A. Background

1. Relevant Statutory and Regulatory Provisions

The Poison Prevention Packaging Act of 1970 ("PPPA"), 15 U.S.C. 1471-1476, authorizes the Commission to establish standards for the "special packaging" of any household substance if (1) the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance and (2) the special packaging is technically feasible, practicable, and appropriate for such substance.

Special packaging, also referred to as "child-resistant" ("CR") packaging, is (1) designed or constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and (2) not difficult for "normal adults" to use properly. 15 U.S.C. 1471(4). Household substances for which the Commission may require CR packaging include (among other

categories) foods, drugs, or cosmetics that are "customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household." 15 U.S.C. 1471(2). The Commission has performance requirements for special packaging. 16 CFR 1700.15, 1700.20.

Section 4(a) of the PPPA, 15 U.S.C. 1473(a), allows the manufacturer or packer to package a nonprescription product subject to special packaging standards in one size of non-CR packaging only if the manufacturer (or packer) also supplies the substance in CR packages of a popular size, and the non-CR packages bear conspicuous labeling stating: "This package for households without young children." 15 U.S.C. 1473(a), 16 CFR 1700.5.

2. Methacrylic Acid

Methacrylic acid ("MAA") is used as a primer before applying artificial fingernails. Nail products containing MAA are cosmetics under the Food Drug and Cosmetic Act ("FDCA"). Although MAA is also used as a chemical intermediate in making some other products, the Commission does not believe that the rule would affect these products.

Nail primers help acrylic overlays adhere to the nail surface. Primers may contain MAA exclusively, but some may have other ingredients. Of the primers that the staff examined, those that do contain MAA have at least 50 percent MAA. Most of the nail primers that contain MAA are labeled

"For Professional Use Only." They are generally distributed through wholesale distributors directly to nail salons and to retail beauty supply stores. Some of these retail stores sell to both professionals and consumers. According to industry sources, there may be as many as 50 nail primer suppliers. Approximately 90 percent of nail primers marketed to professionals contain MAA. The Commission knows of 13 companies that market or have marketed MAA-containing nail primers. Based on industry estimates, the CPSC staff estimates annual unit sales of MAA-containing nail primers at about 1.0 to 1.3 million units in 1/4 oz., 1/2 oz. and larger sizes. These units have a retail value of $4-6.5 million. Their wholesale value is about $2.9 to $4.6 million, based on a 40 percent mark-up typical of the industry.

The industry could not estimate the number of consumers using MAA-containing primers at home. It is clear, however, from the incident data discussed below that these products are used in homes, and children are obtaining access to them. The CPSC staff purchased these primers at retail stores and by mail. This also shows that these products are readily available to consumers.

3. The Proposed Rule

On December 30, 1998, the Commission issued a notice of proposed rulemaking ("NPR") requiring CR packaging for

liquid household products containing more than 5 percent MAA (weight-to-volume) in a single package. 63 FR 71800.

The Commission also mailed copies of the NPR to 150 firms and trade associations that might have an interest in the rulemaking. The Commission received 5 comments in response to the proposed rule. No commenters objected to the proposed rule; three expressed support, and two expressed concern for the professionals applying the primers.

The American Academy of Pediatrics ("AAP"), the American Beauty Association ("ABA") and the Methacrylate Producers Association ("MPA") all wrote in support of the rule. The AAP noted the potential harm to children exposed to MAA and its common use in the home. The ABA, a non-profit trade association representing manufacturers selling more than 80 percent of professional-use beauty salon products, stated that the Commission had fairly weighed the hazards to children and conducted a "fair analysis of the practicality and feasibility of protecting children against the hazards." The MPA, an association of manufacturers of MAA and MAA esters, noted that with the corrosive properties of MAA and the widespread use of primers in the home, the Commission's special packaging proposal is appropriate.

No Lift Nails, a manufacturer of MAA-containing nail primers, expressed concern that no available CR caps would fit a 15 mm bottle finish, and larger bottles would expose

no larger than 1/2 ounce, and that they have a small orifice. The commenter also suggested that the Commission require a restricted flow feature in addition to the small orifice. Under the PPPA, the Commission cannot prescribe a particular packaging design or size. 15 U.S.C. § 1472(d). The Commission can require restricted flow. The Commission is not doing so here because of the small volume applied in a single use and because applicators are commonly inserted into the containers.

Beatrice Kaye Cosmetics commented that MAA poses a serious health problem for professional cosmetologists and their patrons. The PPPA provides the Commission with authority to require CR packaging for substances that pose a hazard to children in the home. It does not give the Commission jurisdiction over hazards unique to professionals in the workplace.

B. Toxicity of Methacrylic Acid

MAA is readily absorbed through mucous membranes of the lungs and gastrointestinal ("GI") tract as well as through the skin. It is rapidly distributed to all majcr tissues, with the highest concentrations in the liver and kidneys. It destroys tissue by chemical action. This makes it a "corrosive" substance as defined in the Federal Hazardous Substances Act. 15 U.S.C. 1261(i).

MAA's effects are similar to those of other acids. As discussed in the NPR, dermal burns, inhalation of acid vapors, ingestion, and eye exposure all can be harmful.

C. Incident Data

The staff reviewed several sources for information of adverse health effects from nail products containing MAA. These sources are published reports in the medical literature, the American Association of Poison Control Centers ("AAPCC"), the FDA Cosmetic Voluntary Registration Program ("CVRP"), and reports from the injury surveillance databases maintained by the Commission. The NPR discusses incident data from those sources in detail.

1. Medical Literature

As discussed in the NPR, two recent articles in the medical literature reviewed relevant data. The first analyzed data from the Toxic Exposure Surveillance System ("TESS"), a database that AAPCC maintains, for 1993 through 1995. Of the 759 reports of exposures to MAA-containing nail products, 564 exposures involved children less than 6 years old. Most of these occurred at home. Approximately 10 percent of young children suffered moderate to major injuries.

The second article reviewed the hazard of nail care products, among them nail primers containing MAA, and reported the medical consequences of ingestion of and/or dermal exposure to primers in two children less than 5 years

old and one adult. The NPR provides details of these incidents.

2. CPSC Databases

The staff reviewed CPSC's databases for poison incidents involving nail primers. As recounted in the NPR, between 1988 and September 30, 1998, the staff identified 85 cases as exposures to nail products specifically identified as primers or as containing MAA. Five of these involved serious injuries resulting from ingestion or dermal exposure to MAA in nail primers. Since publication of the NPR, three additional injuries were reported to CPSC. None of the three children was hospitalized. One incident involved a nail primer that was not confirmed to contain MAA. The other two children suffered burns on their legs after spilling bottles of nail primers known to contain MAA.

3. AAPCC Data

The staff obtained AAPCC data isolating nail products containing MAA for the years 1996 and 1997. The data include 467 exposures, including 341 poisonings (ingestion, ingestion/dermal), 11 ocular exposures, and 115 dermal exposures to children less than 5 years old. No deaths were reported. One poisoning with major medical consequences was reported in 1997. There were 32 poisoning outcomes coded as moderate (10.7 percent) and 137 poisonings (39.3 percent) coded as having minor outcomes. Approximately 90 percent of poisonings occurred in the home.

4. FDA Database

The FDA's CVRP data base contains four reports of injuries from nail primers. One of these reports indicates that a 2-year-old male was brought to the ER after a nail primer splashed in his face and caused burns to the cornea of the eye and the face (1988).

D. Level for Regulation

The Commission is issuing a rule that requires special packaging for household products containing more than 5 percent methacrylic acid in a single package.

At this time, there is no evidence establishing the lowest concentration or amount of MAA capable of causing severe personal injury or illness to young children. Burn severity from corrosive chemicals depends on exposure duration, contact site and product volume, concentration, and chemical characteristics. These chemical characteristics include pH, physical nature, viscosity, titratable acidity or alkalinity, molarity, oxidation-reduction potential, and complexing affinity for bivalent ions. MAA is a weak organic acid closely resembling acetic acid; acetic acid is 1.3-fold more acidic than MAA when concentration is expressed in percent units. As discussed in detail in the NPR, the Commission arrived at a level for regulation based on mutually supportive evidence derived from a report of concentration-related skin injury in mice due to MAA, the calculated pH of various concentrations of

MAA, and the effects of acetic acid on humans at various concentrations.

The actual degree of irritancy or corrosion at 1 to 20 percent concentrations would probably depend on the volume of acid in contact with tissues, the surface area and site affected, and duration of the contact. A concentration of approximately 5 percent MAA does not cause serious injury to mouse skin. It is not likely to be more than a moderate irritant to the eyes of humans, or a mild irritant to the skin of humans. It is equivalent to a 4 percent concentration of acetic acid (about the same as vinegar). That concentration is not associated with serious personal injury or illness in young children. However, concentrations of approximately 10 percent MAA are, at the very least, severe skin irritants in a mouse model and, judging from calculated pH values, are capable of serious eye injury. Because the Commission is not aware of data defining the precise point between 5 and 10 percent at which injury becomes serious, the Commission is requiring child-resistant packaging for products containing more than 5 percent MAA to protect children from potential serious injury. The Commission received no comments on this level.

E. Statutory Considerations

1. Hazard to Children

As noted above, the toxicity data demonstrate that MAA can cause serious illness and injury to children when ingested. Moreover, it is available to children in the form of nail primers that are accessible in the home. These packages are not CR.

Pursuant to section 3(a) of the PPPA, 15 U.S.C. 1472(a), the Commission finds that the degree and nature of the hazard to children from handling and ingesting household products containing MAA requires special packaging to protect children from serious illness. The Commission bases this finding on the toxic nature of MAA-containing products and their accessibility to children in the home.

2. Technical Feasibility, Practicability, and Appropriateness

To issue a standard for special packaging under the PPPA, the Commission must find that the special packaging is "technically feasible, practicable, and appropriate." 15 U.S.C. 1472(a)(2). The Commission may find technical feasibility when technology exists or can be readily developed and implemented to produce packaging that conforms to the standards. Practicability means that special packaging complying with the standards can utilize modern mass production and assembly line techniques. Packaging is

appropriate when complying packaging will adequately protect the integrity of the substance and not interfere with its intended storage or use.

Packaging for MAA-containing nail primers that is senior friendly ("SF") and CR is technically feasible. There are currently available 20 millimeter ("mm") continuous-threaded ("CT") caps without built-in applicator brushes that are SF and CR. The manufacturer of this cap also manufactures a 28 mm CT closure that is CR and SF and has a built in applicator brush. This manufacturer told staff that it could develop a 20 mm CR and SF cap with a built-in applicator brush suitable for use with MAA within one year. Manufacturers of bottles with smaller finishes (the part of a bottle that receives the cap) may have to change to bottles with 20 mm finishes. Some of the smallest sizes of bottles used for MAA-containing primers (0.25 ounces) already have a 20 mm finish. Alternatively, manufacturers could use a restrictive insert to decrease the inside diameter of the bottle opening in conjunction with CR 20 mm finishes.

Special packaging for MAA-containing household products is practicable. CT caps that meet the senior friendly and CR testing requirements have been mass-produced for many years. A 20 mm continuous threaded closure that is CR and SF but lacks an insert for a brush is now mass-produced. Similarly, a 28 mm continuous threaded closure that is CR

and SF and does have an insert for a brush is mass-produced. The mass production and assembly line techniques used for the 28 mm CR and SF closure with insert can be adapted to those used for the 20 mm non-CR closure with an insert and brush.

Special packaging is appropriate when it will protect the integrity of the substance and not interfere with intended storage or use. Nail primers containing MAA are currently packaged in both glass and plastic bottles. Thus, both glass and plastic containers are suitable for MAA-containing products. One packaging manufacturer uses identical materials to produce a 28 mm continuous threaded CR and SF closure (equipped with an insert for attaching a brush) and a 20 mm continuous threaded non-CR closure that is currently used for MAA-containing primers and is equipped with an insert and attached brush. Plastic bottle neck restriction devices should also be compatible with MAA since at least one is already in use. Therefore, the same materials used for non-CR packages of MAA-containing products, with or without brushes or inserts, are used or can be used for CR-packages.

3. Other Considerations

In establishing a special packaging standard under the PPPA, the Commission must consider the following:

a. The reasonableness of the standard;

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

c. The manufacturing practices of affected industries; and

d. The nature and use of the household substance.

15 U.S.C. 1472(b).

The Commission has considered these factors with respect to this rule, and finds no reason to conclude that the rule is unreasonable or otherwise inappropriate.

F. Exemption

The Commission is aware of one MAA-containing primer that is packaged in a tube with a fiber applicator tip. The container looks like a plastic marker pen. The fiber strand holds the MAA so that no free liquid flows through the device. A cap covers the applicator tip. Several manufacturers market this type of device for applying nail primer. Some of these primers contain MAA.

As stated in the NPR, the Commission believes that MAA-containing primers packaged this way do not pose a risk of serious injury. For this type of package not to pose a risk to children, the Commission believes that two conditions must be met: (1) the absorbent material must hold the MAA so that no free liquid is in the device, and (2) through reasonably foreseeable use the MAA will be released only

through the tip of the device. Reasonably foreseeable use would include reasonably foreseeable abuse by children. These conditions are grounded in an existing exemption from FHSA labeling for porous-tip ink-marking devices. 16 CFR 1500.83(a)(9).

The volume of MAA available and accessible is extremely small (total amount of material in the devices is reportedly less than 1/2 gram). The only possible route of serious injury would be from direct contact of the felt tip with the eye. The staff has not identified any incidents involving these types of devices. Thus, the Commission is exempting MAA-containing primers contained in these marker-like devices if they meet the conditions discussed above.

G. Effective Date

The PPPA provides that no regulation shall take effect sooner than 180 days or later than one year from the date such final regulation is issued, except that, for good cause, the Commission may establish an earlier effective date if it determines an earlier date to be in the public interest. 15 U.S.C. 1471n.

As proposed, the Commission is providing a one-year effective date. Currently, 20 mm CT caps that are CR and senior friendly are available. However, these caps are not available with a built-in applicator brush. Thus, manufacturers will need to make some modifications to provide a CR cap with a built-in applicator. Such closures

should be available within one year. The Commission received no comments respecting the effective date.

Thus, the rule will take effect 12 months after publication and will apply to products that are packaged on or after the effective date.

H. Regulatory Flexibility Act Certification

When an agency undertakes a rulemaking proceeding, the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, generally requires the agency to prepare proposed and final regulatory flexibility analyses describing the impact of the rule on small businesses and other small entities. Section 605 of the Act provides that an agency is not required to prepare a regulatory flexibility analysis if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The Commission's Directorate for Economic Analysis prepared an assessment of the impact of a rule to require special packaging for household products containing more than 5 percent methacrylic acid. As discussed in the NPR, based on this assessment the Commission certified that the rule is not likely to have a substantial effect on a significant number of small businesses. The Commission requested suppliers, particularly small businesses, to provide information on the impact the proposed rule would have on them, but did not receive any such comments.

I. Environmental Considerations

As noted in the NPR, the Commission assessed the possible environmental effects associated with the proposed PPPA requirements for MAA-containing products and found that the rule would have little or no potential for affecting the human environment. The Commission concluded that neither an environmental assessment nor an environmental impact statement is required.

J. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations. As explained in the NPR, the rule requiring CR packaging for household products containing more than 5 percent MAA would preempt non-identical state or local special packaging standards for such MAA-containing products.

In accordance with Executive Order 12612 (October 26, 1987), the Commission certifies that the rule does not have sufficient implications for federalism to warrant a Federalism Assessment.

List of Subjects in 16 CFR Part 1700

Consumer protection, Cosmetics, Infants and children, Packaging and containers, Poison prevention, Toxic substances.

For the reasons given above, the Commission amends 16 CFR part 1700 as follows:

PART 1700--[AMENDED]

1. The authority citation for part 1700 continues to read as follows:

Authority: Pub. L. 91-601, secs. 1-9, 84 Stat. 1670-74, 15 U.S.C. 1471-76. Secs 1700.1 and 1700.14 also issued under Pub. L. 92-573, sec. 30(a), 88 Stat. 1231. 15 U.S.C. 2079(a).

2. Section 1700.14 is amended by adding new paragraph (a)(28) to read as follows (although unchanged, the introductory text of paragraph (a) is included below for context):

§ 1700.14 Substances requiring special packaging.

(a) *Substances.* The Commission has determined that the degree or nature of the hazard to children in the availability of the following substances, by reason of their packaging, is such that special packaging meeting the requirements of § 1700.20(a) is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances, and the special packaging herein required is technically feasible, practicable, and appropriate for these substances:

* * * * *

(29) *Methacrylic acid.* Except as provided in the following sentence, liquid household products containing more than 5 percent methacrylic acid (weight-to-volume) in a single retail package shall be packaged in accordance with the provisions of § 1700.15(a),(b) and (c). Methacrylic acid products applied by an absorbent material contained inside a dispenser (such as a pen-like marker) are exempt from this requirement provided that: (i) the methacrylic acid is contained by the absorbent material so that no free liquid is within the device, and (ii) under any reasonably foreseeable conditions of use the methacrylic acid will emerge only through the tip of the device.

Dated: _____

_____
Sadye E. Dunn,
Secretary, Consumer Product Safety Commission

List of Relevant Documents

1. Briefing memorandum from Susan Aitken, Ph.D., EH, to the Commission, "Proposed Special Packaging Standard for Household Products Containing Methacrylic Acid," November 23, 1998.

2. Memorandum from Susan Aitken, Ph.D., EH, to Mary Ann Danello, Ph.D., Associate Executive Director, EH, "Toxicity of Methacrylic Acid" August 12, 1998.

3. Memorandum from Susan C. Aitken, Ph.D., EH, to Mary Ann Danello, Ph.D., EH, "Human Injuries from Nail Products Containing Methacrylic Acid," August 12, 1998.

4. Memorandum from Marcia P. Robins, EC, to Susan Aitken, Ph.D., EH, "Economic Considerations: Proposal to Require Child-Resistant Packaging for Household Products Containing Methacrylic Acid," August 17, 1998.

5. Memorandum from Tewabe A. Asebe, EH, to Susan Aitken, Ph.D., EH, "Technical Feasibility, Practicability, and Appropriateness Determination for Proposed Rule to Require Special Packaging for Methacrylic Acid-Containing Products," August 17, 1998.

6. Memorandum from Bhooshan Bharat, Ph.D., LS, and Bhavi K. Jain, MS, LS, "Report on the Testing of Nail Products for Titratable Acid Reserve ("TAR"), Quantification of Methacrylic Acid, and pH," August 20, 1998.

7. Briefing memorandum from Susan Aitken, Ph.D., EH, to the Commission, "Final Rule to Require Child-Resistant Packaging for Household Products Containing More Than 5 Percent Methacrylic Acid in a Single Package," May __, 1999.

8. Memorandum from Marcia P. Robins, EC, to Susan Aitken, Ph.D., EH, "Final Rule for Child-Resistant Packaging for Household Products Containing Methacrylic Acid: Regulatory Flexibility Issues," April 8, 1999.

9. Memorandum from Tewabe A. Asebe, EH, to Susan Aitken, Ph.D., EH, "Assessment of Technical Feasibility, Practicability, and Appropriateness for the Final Rule to Require Child-Resistant Packaging for Methacrylic Acid Products," April 23, 1999.