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).