Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 99–CE–23–AD.'' The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein will 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 final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and is not a significant regulatory action under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket (otherwise, an evaluation is not required). A copy of it, if filed, may be obtained from the Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 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:

99–13–04 Cessna Aircraft Company: Amendment 39–11197; Docket No. 99–CE–23–AD.

Applicability: The following airplane model and serial number airplanes, certificated in any category:

Models	Serial numbers
206H ... T206H	20608002 through 20608026. T20608002 through T20608015; T20608017 through T20608023; and T20608025 through T20608028.

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 (e) 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 detect and correct loose aileron control bellcrank stop bolts, which could result in restricted movement of the aileron with possible partial or complete loss of aileron control, accomplish the following:

(a) Within the next 10 hours time-in-service after the effective date of this AD or within the next 60 calendar days after the effective date of this AD, whichever occurs first, inspect the left and right wing aileron control bellcrank stop bolts and lock nuts for flush and tight contact with the surface of the threaded boss on each end of the yoke assemblies. Accomplish this inspection in accordance with the INSPECTION/MODIFICATION INSTRUCTIONS section of Cessna Special Service Project SSP99–27–02, dated May 18, 1999.

(b) If the bolts and nuts are flush and tight, or loose but flush after tightening, prior to further flight, accomplish the following actions in accordance with the INSPECTION/MODIFICATION INSTRUCTIONS section of Cessna Special Service Project SSP99–27–02, dated May 18, 1999:

(1) Loosen nuts;
(2) Clean threads (bolt and nut);
(3) Wick Loctite 290 into threads; and
(4) Torque nut.

(c) If the bolts and nuts are not flush, prior to further flight, accomplish the following actions in accordance with the INSPECTION/MODIFICATION INSTRUCTIONS section of Cessna Special Service Project SSP99–27–02, dated May 18, 1999:

(1) Remove nut and stop bolt;
(2) Spotface boss;
(3) Clean threads (boss, bolt, and nut);
(4) Apply Loctite 242;
(5) Adjust stop bolt; and
(6) Torque bolt.

Note 2: Paragraphs (b) and (c) of this AD present a basic outline of the follow-on work to be accomplished. The detailed procedures to accomplish these actions are included in the INSPECTION/MODIFICATION INSTRUCTIONS section of Cessna Special Service Project SSP99–27–02, dated May 18, 1999.

(d) 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.

(e) An alternative method of compliance or adjustment of the compliance times that provides an equivalent level of safety may be approved by the Manager, Wichita Aircraft Certification Office (ACO), 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas, 67209. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Wichita ACO.

(f) The inspections and follow-on actions required by this AD shall be done in accordance with Cessna Special Service Project SSP99–27–02, dated May 18, 1999. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Cessna Aircraft Company, P.O. Box 7706, Wichita, Kansas 67277–7706. Copies may be inspected at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(g) This amendment becomes effective on July 13, 1999.

Issued in Kansas City, Missouri, on June 10, 1999.

Michael K. Dahl,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–15220 Filed 6–17–99; 8:45 am]

BILLING CODE 4910–13–P

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 June 19, 2000 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, DC 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 ¼ oz., ½ 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 more cosmetologists to MAA because of spills. The commenter suggested that the Commission require that bottles be both no larger than ½ 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 major 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 ½ 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. In § 1700.14 the introductory text of paragraph (a) is republished and paragraph (a)(29) is added 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: (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: June 15, 1999.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

Note: The following list will not appear in the Code of Federal Regulations.

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 21, 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.

[FR Doc. 99–15580 Filed 6–17–99; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. 98C–0158]

Listing of Color Additives For Coloring Meniscal Tacks; D&C Violet No. 2

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of D&C Violet No. 2 to color absorbable meniscal tacks made from poly(L-lactic acid). This action responds to a petition filed by Linvatec Corp.

DATES: This regulation is effective July 20, 1999; except as to any provisions that may be stayed by the filing of proper objections; written objections and requests for a hearing by July 19, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3089.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of March 13, 1998 (63 FR 12473), FDA announced that a color additive petition (CAP 8C0255) had been filed by Linvatec Corp., P.O. Box 2917, Largo, FL 33779–2917. The petition proposed to amend the color additive regulations in § 74.3602 *D&C Violet No. 2* (21 CFR 74.3602) to provide for the safe use of D&C Violet No. 2 to color absorbable meniscal tacks made from poly(L-lactic acid). The petition was filed under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379e(d)(1)).