



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

CPSC/OFFICE OF
 THE SECRETARY

1998 NOV 25 A 10: 06

VOTE SHEET

DATE: NOV 23 1998

TO : The Commission
 Sadye E. Dunn, Secretary

FROM : Jeffrey Bromme, General Counsel *JB*
 Stephen Lemberg, Assistant General Counsel *SL*

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

Attached is a staff briefing package recommending that the Commission issue a proposed 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 F 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 rls Date 11/23/98

CPSC is (B)(1) Closed

No Mirc/Prvillix or Products Identified Excepted by Rulemaking *11-23-98 #B*

III. Do not approve the draft Federal Register notice.

(Signature)

(Date)

IV. Take other action (please specify).

(Signature)

(Date)

Attachment

Briefing Package

Proposed Rule to Require Child-Resistant
Packaging for Household Products Containing Methacrylic Acid

For Information Contact:

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NOTE: This document has not been
reviewed or accepted by the Commission.
Initial RA Date: 11/23/96

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CPSA 6 (b)(1) Cleared 11-23-98
 No Mins/Provbltrs or
Products Identified Rulemak's

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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. The Food and Drug Administration regulates cosmetics such as nail products under Section 201 of the Federal Food, Drug, and Cosmetic Act. In addition, the Commission can require a special packaging standard for cosmetics under Section 2(b) of the Poison Prevention Packaging Act (PPPA).

Acute effects of methacrylic acid in nail primers range from slight irritation to severe corrosive injury on contact with skin, eyes, or mucous membranes. The medical literature and evidence from collected samples demonstrate that nail primers can contain high concentrations of methacrylic acid and are generally not in child resistant (CR) packaging. The staff determined that household products containing more than 5 percent methacrylic acid can cause serious personal injury and illness to children less than 5-years-old, and that products containing 5 percent or less methacrylic acid can cause little or no personal injury or illness.

Data support a 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 determined that CR packaging is available or can be developed within one year of publication of a final rule.

Staff review of market information indicates that small businesses dominate the professional nail preparation supply industry. Although a special packaging requirement for household products containing methacrylic acid may affect many small businesses, the impact on any individual supplier is expected to be minimal. Incremental costs for CR packaging are typically low relative to retail costs and are expected to be passed on to users. Staff analysis also indicates that the proposed rule will have no significant impact on the environment.

The staff recommends that the Commission propose a special packaging standard for liquid household products containing more than 5 percent methacrylic acid on a weight-to-volume (w/v) basis. The staff also recommends that dispensers (i.e. pen-like devices) 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.



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

MEMORANDUM

DATE: NOV 23 1998

TO : The Commission
 Sadye E. Dunn, Secretary

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

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

SUBJECT : Proposed 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. 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. Exposure to MAA in nail primers is known to cause serious injury due to its corrosive effects on skin, eyes, and mucous membranes. This memorandum reviews available toxicity, injury, marketing, and packaging information for household products containing MAA. At this time, some types of nail primers are the only household products confirmed to contain MAA.

Cosmetic nail products are regulated by the Food and Drug Administration (FDA) under Section 201 of the Federal Food, Drug, and Cosmetic Act (FFDCA). However, the U.S. Consumer Product Safety Commission (CPSC) can require a special packaging standard for cosmetics for household use under Section 2(b) of the Poison Prevention Packaging Act (PPPA). The Commission has required child-

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 No Mfrs/Prvtlbrs of Products Identified *11-23-98 RLM*

resistant (CR) packaging for cosmetics in the past. Acetonitrile is found in glue removers for artificial nails, as well as glue removers for cyanoacrylate household glues and certain products used by hobbyists. Because accidental ingestion of acetonitrile was associated with serious personal injury or harm to children less than 5-years-old, the Commission required household glue removers in liquid form containing more than 500 mg acetonitrile in a single container to be placed in CR packaging [16 CFR § 1700.14(a)(18)]. The Commission similarly established special packaging standards for home permanent neutralizers in liquid form, containing a) more than 600 mg of sodium bromate or b) more than 50 mg of potassium bromate [id. § 1700.14(a)(19)]. In addition, certain cosmetic mouthwash products containing 3 grams or more ethanol in a single package are subject to a special packaging standard [id. § 1700.14(a)(22)].

II. Discussion

A. Potential for Serious Human Injury (Toxicity, TAB A)

MAA is a weak organic acid resembling acetic and formic acids. Both animal and human data indicate MAA can cause acute effects ranging from slight irritation to severe corrosive injury on contact with skin or mucous membranes. Under the Federal Hazardous Substances Act (FHSA), a corrosive refers to any substance which in contact with living tissue will cause destruction of tissue by chemical action [15 U.S.C. 1261(i)]. Although MAA is readily absorbed through mucous membranes of the lungs and gastrointestinal (GI) tract as well as through intact skin, little information is available concerning acute effects on other organ systems or other tissues.

Concentrated MAA (99 percent) is corrosive to rabbit skin at all sites tested, even with brief 3 minute exposures to low volumes [0.5 milliliters (ml)] followed by immediate washing. Severity of injury is concentration-dependent with little effect on the skin of the mouse at 4.8 percent and severe irritation/corrosion at concentrations of 9.6 percent or more. In addition, concentrated MAA is corrosive to the eyes of rabbits. Undiluted MAA (0.1 ml) caused corneal opacity and severe injury to the iris and conjunctiva even when these tissues were rinsed within 4 seconds after instillation. Effects persisted for at least 7 days. Concentrated MAA is also corrosive to mucous membranes of the GI tract. A single oral gavage of 2 ml MAA (2 g/kg body weight) caused severe gastric irritation in rats.

In human experience, MAA is a known corrosive agent via inhalation, ingestion, or dermal contact. Undiluted MAA is corrosive to skin, eyes, and mucous membranes and diluted MAA, depending on the concentration and duration of exposure, can produce skin irritation, ocular and corneal damage, nasal lesions, and irritation to GI mucous membranes.

In general, the effects of MAA on skin, eyes, and mucous membranes resemble those of other acids. Dermal burns can result in destruction of surface epithelium and submucosa with associated damage to blood vessels and connective tissue. Exposure via inhalation of acid vapors can produce marked nasal irritation, salivation, difficulty breathing, pleuritic chest pain, and bronchospasm. Ingestion generally results in mild to severe burns to the oral cavity, esophagus, and other GI organs. The pyloric end of the stomach tends to be most severely affected. GI bleeding, perforation, edema, necrosis, stenosis (narrowing of the GI passage), fistulas (abnormal passages or outpocketings), and intestinal injuries can occur. Areas of stricture can develop about 3 weeks post-ingestion. Eye exposure can result in pain, swelling, corneal erosions, and blindness. It can take 48 to 72 hours to correctly assess the degree of eye injury. Degree of ocular injury is primarily a function of pH; pH levels below 2.5 are associated with more severe injuries.

B. Evidence of Serious Human Injury (Case Reports, TAB B)

The case reports summarized below document the serious personal injury and harm incurred by children less than 5-years-old due to accidental exposure to nail primers containing methacrylic acid.

Medical Literature

A recent article in the medical literature described the personal consequences of ingestion and/or dermal exposure to primers in two children less than 5-years-old (Linden et al., 1998). The first case was that of a 21-month-old male who accidentally ingested approximately 3 to 5 ml of a nail primer containing at least 98 percent MAA. He required endotracheal intubation to maintain the airway. Endoscopy revealed severe tissue damage to the upper GI tract, pharynx, and airways. He was hospitalized for approximately one month, and one year later, x-rays confirmed a stricture of the esophagus. Skin burns on the lips, chin, and neck resolved without permanent scarring.

The second case was that of a 2-1/2-year-old male who spilled approximately 5-7 ml of a nail primer containing at least 98.5 percent MAA onto his face, right arm, and chest. The affected areas were immediately rinsed with water, and he was treated at a nearby hospital 20 minutes later. ER personnel noted patchy redness of the face, chest, right arm, and flank. Blisters developed on his chest. All burn areas healed without scarring. Additional details on these incidents as well as similar injuries to an adult are in TAB B.

AAPCC Injury Case Reports

The AAPCC provided 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 a home (either the child's own residence or in someone else's residence). A summary of the more significant cases from the collection follows below. Additional case reports are described in TAB B.

In the only incident occurring outside the home, 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. During this period, she received acetaminophen for pain and antibiotic ointment to prevent infection of the blisters on her lips. Blisters on her cheeks were open. On the third day, she was transferred to a regular bed and her 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 1-1/2 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 three 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.

CPSC Injury Case Reports

In-Depth Investigations (IDIs) conducted by CPSC staff provided details on injuries due to nail primers. Several of these IDIs are summarized below; these and additional IDIs are further discussed in TAB B. Nail primers, occasionally described as nail bonding agents, are available in several formulations, but only MAA-containing nail primers are known to be capable of inflicting potentially serious burns on immediate contact with skin, eyes, or mucous membranes. Staff has determined that all other cosmetic products termed nail primers or nail bonding agents are mild to moderate irritants, and do not present the corrosive hazard of MAA. Staff therefore assumed that, when formulation was not specifically

identified, the causal agent in a serious injury due to nail primers was MAA. The records for the cases described below indicate that victims suffered immediate intense pain and incurred serious burns, strongly suggesting exposure to MAA.

A 2-year-old female accessed 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 1-1/2 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 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. She was treated and released the same day.

A 2-year-old male accessed an artificial nail kit left on a living room table. The child was about to ingest the bonding agent (primer) when he spilled about 1-1/2 ounces on his shirt and around his mouth and nose. He was immediately taken to the emergency room (ER) where the burns he received from the spill were treated. He remained in the hospital under observation for two nights, and was then transferred to another hospital for an endoscopy because of difficulty swallowing. He 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 1 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.

FDA Injury Case Reports

The FDA's Cosmetic Voluntary Registration Program (CVRP) compiles manufacturers' reports of adverse reactions experienced by their customers as well as direct reports to the FDA from consumers, doctors, nail technicians, and manufacturers' competitors. The CVRP data base contains one report of injury to a child less than 5-years-old due to a nail primer. 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).

C. Epidemiology of Human Injury (Injury Data Bases, TAB B)

The following information documents the frequency of exposures and serious injuries following access of children less than 5-years-old to nail primers containing methacrylic acid.

TESS Injury Data Base

The Toxic Exposure Surveillance System (TESS) is a data base maintained by the American Association of Poison Control Centers (AAPCC). The 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 TESS. The poison control centers serve approximately 85 percent of the U.S. population, but data do not represent a probability sample.

A recent article in the medical literature addressed general patterns of injuries due to nail products as a whole and nail primers containing MAA in particular (Wolfe and Shaw, 1998). The authors analyzed TESS data for the years 1993 through 1995 by retrospectively examining text details in individual case reports. The CPSC staff ordinarily do not have access to individual case records collected by the AAPCC, and therefore restrict discussion to the data as compiled and presented by the authors.

MAA-containing nail products accounted for 564 reports of exposures to children less than 6-years-old during the 3-year period between 1993 and 1995. Most incidents involved mixed dermal/ingestion or dermal exposures in the home. Approximately 10 percent of young children suffered moderate to major injuries¹. The data did not show concentration-related differences in severity of injuries at concentrations of MAA ranging from 70 to 100 percent, suggesting the potential for injury at these high concentrations was identical. The data were also analyzed using a product hazard score devised by AAPCC analysts. The hazard score for nail products containing MAA was very high (8.6), virtually the same as nutritional supplements containing iron (8.5), and much higher than cosmetics as a group (0.2). An explanation of the hazard score is on page 7 of TAB B.

CPSC staff obtained compiled TESS data isolating nail products containing MAA for the subsequent 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 was discussed previously as one of several AAPCC case reports. Thirty-two poisoning outcomes were coded as moderate (10.7 percent) and 137 poisoning outcomes (39.3 percent) were coded as minor. Ten additional poisoning incidents were coded as not followed but, in the judgment of the coder, may have had toxic effects. Approximately 90 percent of poisonings occurred in the home (the child's residence or another personal residence).

¹ **Minor Symptoms** - The patient exhibited some minimal signs or symptoms which resolved rapidly.
Moderate Symptoms - 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 the patient returned to a pre-exposure state of well-being with no residual disability or disfigurement.
Major Symptoms - The patient exhibited some symptoms which were life-threatening or resulted in disfigurement or residual disability.

CPSC Injury Data Bases

Data compiled from CPSC injury data bases² correspond closely with the above TESS data. Staff reviewed data base records dating from January, 1978 through September 30, 1998. Nail products specifically identified as primers or as containing MAA were cited in 85 case records (84 in NEISS, one in IPII) between January 1, 1988 and September 30, 1998.

Records in NEISS can yield national estimates of injuries treated in emergency rooms when a sufficient number of incidents are entered in the data base³. 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 as described in TAB B. An estimated 2,723 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 estimated ER visits (2,272).

Conclusions - Human Injury Data

The TESS data indicate that a minimum of approximately 188 children less than 6-years-old accessed nail primers containing MAA annually during the years 1993 through 1995, and at least 467 (233 annually) children less than 5-years-old accessed nail primers containing MAA in the 2 year period between 1996 and 1997. Approximately 90 percent of these children accessed MAA-containing nail primers in the home, and approximately 10 percent of children experienced severe injuries as a consequence of that access. The NEISS data suggest that an estimated 160 to 335 children less than 5-years-old are treated in hospital ERs annually due to exposure to nail primers. In close agreement with the TESS data, approximately 83 percent of these children accessed these nail primers in the home, and approximately 10 percent of these children required hospitalization.

² CPSC data bases include the National Electronic Injury Surveillance System (NEISS, January 1, 1988 - September 30, 1998), the Injury and Potential Injury data base (IPII, January 1, 1980 - September 30, 1998), the In-Depth Investigations data base (INDP, January 1, 1980 - September 30, 1998), the Death Certificate data base (DHS, January, 1980 - September 30, 1998), and the Children and Poisonings data base (CAP, January, 1973 - December, 1987). Details on these data bases are in TAB B.

³ Several caveats, discussed below and in greater detail in TAB B, apply to the extension of NEISS incident data on nail primers to national estimates of the absolute number of ER visits attributable to nail primers containing MAA. 1) The number of actual reports of ER visits due to nail primers containing MAA is not certain. Some NEISS reports did not provide sufficient detail to conclude that the nail primer implicated in a specific exposure contained MAA, and it is also possible that the total of 395 incidents involving types of nail products other than primers could include some additional injuries due to MAA-containing nail primers. 2) The number of NEISS reports of injuries due to nail primers was less than 20 per year. Staff do not ordinarily use fewer than 20 annual reports of injuries to obtain annual estimates; the data in this case were pooled to obtain an 11-year estimate. 3) Zero-weighted cases are not part of the probability sample used to compute national estimates. Only 63 of the 85 primer case reports contributed to the estimates.

As noted previously, nail primers are available in several formulations, but only MAA-containing nail primers are known to be capable of causing immediate symptoms (pain and burns) likely to precipitate ER visits and require hospitalization.

The data from available injury data bases, and case reports from the medical literature, the AAPCC, the FDA, and the CPSC cumulatively establish 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.

D. Level for Regulation (TAB A)

Human evidence associates skin and mucous membrane contact with as little as 3-5 ml of 70-99 percent MAA with severe corrosive effects. MAA is also capable of causing serious eye injury at the high concentrations present in nail primers. Although the lowest amount of MAA actually likely to produce serious injury to humans is not clearly defined, the properties of acetic acid closely resemble those of MAA. Considerable information is available concerning the effects of different concentrations of acetic acid in humans. Staff arrived at a level for regulation based on mutually supportive evidence derived from 1) a report of concentration-related skin injury in mice due to MAA; 2) the known pH and effects of acetic acid at various concentrations; and 3) the calculated pH values of MAA solutions at different concentrations.

Human evidence does not associate exposures to commercial vinegar (4 to 6 percent acetic acid) with burns but suggests vinegar can cause mild irritation to skin. The Toxicological Advisory Board (U.S. CPSC, 1982) similarly recommended that 5 percent concentrations of acetic acid be considered a weak skin irritant. However, concentrations 2- and 4-fold higher require stronger warnings. The Toxicological Advisory Board rated 10 percent acetic acid as a strong skin irritant, and acetic acid concentrations of 20 percent warrant labeling as poisons under the FHSA [16 CFR 1500.129].

In similar fashion, 2-fold changes in MAA concentration also cause increasing levels of injury. A study in mice suggests that 4.8 percent MAA would probably act, at most, as a mild skin irritant to humans, even when in solution in acetone. However, doubling that concentration to 9.6 percent MAA causes severe irritation equivalent to second degree burns to the skin. Doubling the concentration again to 19.2 percent results in visible destruction to skin epithelium and injuries throughout all layers of the skin bordering on corrosive.

In general, solutions with a pH at or above 2.5 do not cause serious or permanent damage to the eye. A solution of 3 percent acetic acid, pH 2.53, is considered a moderate eye irritant. A 5 percent solution of acetic acid, pH 2.47, is also considered a moderate irritant. Moderate degrees of injury to the eyes are not corrosive; corneal opacity and inflammatory changes in the eye and its surrounding mucous membranes are reversible. However, a 10 percent solution of acetic acid, pH 2.28, is severely irritating and may be corrosive, depending on the length of exposure and the volume contacting the eyes.

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). A 4.8 percent solution of MAA has a pH of 2.46, and, judging from the effects of acetic acid, probably would also be considered a moderate eye irritant. Doubling the MAA concentration to 9.6 percent produces a solution with a pH of 2.3; this solution is a probable severe eye irritant and may be corrosive. 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 chemical solutions tends to increase the degree of injury to eyes, mucous membranes of the GI and respiratory tract, and skin. Since MAA is relatively insoluble in aqueous solutions, concentrations of 9 percent or greater MAA would have to be dissolved 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, surface area, site affected, and duration of contact. A concentration of approximately 5 percent MAA does not cause serious injury to mouse skin, is not likely to be more than a moderate irritant to eyes of humans or a mild irritant to the skin of humans, and 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 solutions containing 5 percent MAA will not cause serious personal harm or illness in young children. Since the staff are not aware of data defining the precise point between 5 and 10 percent at which injury becomes serious, the staff recommend that child-resistant packaging be required for products containing more than 5 percent MAA to protect children from potential serious injury or illness. The staff recommend that the Commission solicit comment on this level.

E. Economic Information (TAB C)

The staff reviewed the consumer market for household products containing MAA and summarized the information available from manufacturers, trade association representatives, scientific journal articles, and the trade press. Two separate industry groups represent companies that market nail primers. The Cosmetic, Toiletry, and Fragrance Association (CFTA) represents companies that primarily market to consumers. According to a CFTA spokesperson, an informal survey of CFTA membership suggested member companies do not market nail primers containing MAA.

The Nail Manufacturers' Council (NMC) represents suppliers who largely market primers directly to beauty/nail salons and retail beauty supply stores. These products are intended for use by professional nail technicians. Although other formulations of nail primers are available, an estimated 90 percent of primers marketed to professionals contain MAA. Some of these beauty supply stores sell products to professionals and consumers alike. Staff of the Directorate for Economic Analysis (EC) were able to purchase nail primers, some of which were labeled "Professional Use Only" from beauty supply retail stores and a beauty supply mail order company. Documentation of professional status was not required.

According to the NMC, the professional nail preparation supply industry is dominated by small businesses. There may be as many as 50 nail primer suppliers that purchase MAA in bulk, repackage in small bottles (0.25 to 2 ounces), and market to beauty/nail salons and retail beauty stores. EC staff specifically identified 13 companies marketing MAA-containing nail primers; seven of these companies may be considered small businesses. Although there are no firm estimates of market share, and the list of leading suppliers for MAA-containing primers differs slightly with the source of information, the five leading suppliers may share up to 90 percent of the market. EC staff preliminarily estimated that annual retail sales of MAA-containing primers amount to between \$4 and \$6.5 million, equivalent to product wholesale values of \$2.9 to \$4.6 million. The unit sales may amount to 1 to 1.3 million units in 1/4 ounce, 1/2 ounce, and 2 ounce bottles.

No information is available at this time concerning the incremental cost of CR packaging. Typically, incremental costs for CR packaging are low relative to retail cost. Moreover, incremental costs for special packaging of primers would be passed on to users. Although a special packaging requirement for household products containing MAA may affect many small businesses, the impact on any individual supplier is expected to be minimal.

In order to obtain more complete information concerning the impact of a special packaging requirement on small businesses, the draft NPF requests that suppliers submit product information and comment on the effects of the proposed rule. EC staff compiled a mailing list of over 100 firms and organizations that may be affected by the rule. If the Commission decides to propose a regulation, the staff will send the FR notice to each of these parties.

Preliminary analysis indicates that the proposed rule will have no significant impact on the environment. The manufacture, use, and disposal of CR and non-CR closures result in identical environmental effects.

F. Available Packaging

EHHS staff evaluated the packaging of ten nail primer products (TAB D). Laboratory results (TAB E) confirmed that five of these products contained MAA in concentrations ranging from approximately 50 to 100 percent. All five had pH levels below 2.5, and all five were packaged in 0.25 to 2 ounce bottles with 13-20 millimeter (mm) non-CR continuous threaded plastic closures. Three of these packages included a built-in applicator brush, one had a separate applicator brush, and one completely lacked an applicator brush. NMC representatives commented that nail primer manufacturers prefer packages with attached brushes for safety reasons, believing the cap is more likely to be replaced on the bottle and the brush is less likely to be left unsecured and accessible. One manufacturer of MAA-containing primers is also using a restrictive insert in the neck of the bottle to decrease the size of the access hole. A brush attached to the closure fits through the bottle neck in this particular package design.

G. Technical Feasibility, Practicability, and Appropriateness

The EHHS staff review (TAB D) supports a conclusion that a special packaging standard for household products containing MAA is technically feasible in that technology is now available or can be readily developed to produce packaging that conforms to special packaging standards. One packaging manufacturer produces both a 28 mm continuous threaded CR and senior friendly (SF) closure with an insert for attaching a brush and a 20 mm CR and SF continuous threaded closure without an insert for a brush. This manufacturer states that a 20 mm continuous threaded CR and SF closure that is useable with MAA-containing primers and has an insert for the option of attaching a brush can be produced. Manufacturers of bottles with smaller finishes 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. In addition, manufacturers of MAA-containing primers have the option of using a variety of commercially available restrictive inserts to decrease the inside diameter of the bottle opening. One manufacturer of MAA-containing primers currently uses such a restriction.

Special packaging is practicable in that packaging complying with PPPA standards can be mass produced using modern assembly line techniques. 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. Data support a conclusion that special packaging, with or without a brush, for MAA-containing products is practicable.

Special packaging is appropriate in that it protects the integrity of MAA and will not interfere with its intended use. 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. Data support a finding that special packaging is appropriate.

III. Exemptions

At least one primer that contains MAA is packaged in a plastic marker style of package with a fiber applicator tip, preventing any substantial flow or spillage of free liquid from the device. The tip is actually the exposed portion of a continuous strand of fiber occupying the interior of the pen. A non-CR overcap shields the applicator tip. Several manufacturers market similar styles of packaging.

Under the FMSA, some porous-tip ink-marking devices are exempt from labeling requirements for toxic substances [16 CFR 1500.83(a)(9)]. One of the conditions for such an exemption is that the ink will emerge only through the porous tip under any reasonable conditions of manipulation and use. A second condition is that an interior absorbent material ensures that no free liquid is contained within the device. The construction of these pens appears to meet both of these conditions. One distributor of the pens reports that they are shipped empty and filled by the customer by dipping the fiber tip into a bottle for a few minutes, wicking the primer liquid up into the pen. A second distributor ships similar pens already filled with MAA. These pens also contain a wicking material, ensuring that no free liquid is available. The total amount of material taken up into the pens reportedly does not exceed 1/2 gram.

It may be possible to develop a lug finish CR closure for the overcap on pen devices. However, staff do not believe, based on the construction and design of the pens that the pens constitute a serious hazard to children less than 5-years-old.

The volume of available and accessible MAA is extremely small, and HS staff believes the only possible route of serious injury would lie in direct contact of the felt tip with the eye. HS staff identified no MAA exposures involving pen devices, and the probability of serious injury specifically to the eye from these devices appears low. At this time, staff believe MAA-containing devices with the above design should be exempted from a requirement to comply with a special packaging standard.

IV. Effective Date

Section 9 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. Packages with 20 mm continuous threaded SF and CR closures, with or without applicators and compatible with MAA-containing products, can be available within a year. This includes time for closure manufacturers to produce the 20 mm closures and 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. Staff recommend an effective date of one year.

V. Options

1. The Commission may propose a rule requiring special packaging for household products containing more than 5 percent MAA (weight-to-volume, w/v) if the Commission preliminarily finds that:

i) special packaging is required to protect young children from serious personal injury or illness from handling, using, or ingesting the product; and

ii) special packaging is technically feasible, practicable, and appropriate.

2. The Commission may decline to propose a rule if it is unable to make the necessary findings.

VI. Conclusion and Recommendation

MAA is a corrosive substance contained in artificial fingernail 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. Samples of nail primers containing MAA that were collected by staff are not in CR packaging. Staff determined that CR packaging is available or can be developed within one year of a final rule.

Based on available information, the staff recommends that the Commission propose a special packaging standard for liquid household products containing more than 5 percent methacrylic acid on a weight-to-volume (w/v) basis. The staff also recommends that dispensers (i.e. pen-like devices) 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.

TAB A



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

MEMORANDUM

AUG 12 1998

DATE :

TO : Mary Ann Danello, Ph.D., Associate Executive Director, Directorate
for Epidemiology and Health Sciences (EH)

THROUGH : Marilyn L. Wind, Ph.D., Director, Division of Health Sciences *MRW*

FROM : Susan C. Aitken, Ph.D., Pharmacologist, Division of Health Sciences *SCA*

SUBJECT : Toxicity of Methacrylic Acid

Toxicity of Methacrylic Acid

Introduction

Under the Poison Prevention Packaging Act (PPPA) of 1970, the Commission can require a special packaging standard for hazardous household substances. This action is dependent on the finding that the availability of any such substance, by reason of its packaging, is such that special packaging is required to protect children less than 5-years-old from serious personal injury or illness due to handling, using, or ingesting such a substance.

Methacrylic acid is a chemical used as a component of dental fillings, a chemical intermediate in the manufacture of resins, paints, adhesives, paper, polishes, and plasticizers, and a primer for cleaning, degreasing, dehydrating, and etching fingernails prior to applying artificial nails. The major use in consumer products is in nail care products. Recently, a series of injuries involving nail primers containing methacrylic acid prompted Commission staff to review the hazard of these products to determine the possible need for action under the PPPA. This memorandum will present the available scientific data providing evidence of illness and injury caused by methacrylic acid, emphasizing data relevant to childhood accidental ingestions or injuries.

Discussion

I. Regulatory Information

Nail products for both home and salon use are regulated by the Food and Drug Administration (FDA). Under Section 201 of the Federal Food, Drug, and Cosmetic Act (FFDCA), these products are considered cosmetics because they are "articles other than soap which are applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance." By law, nail products sold as cosmetics in the United States must be free of poisonous or deleterious substances that might injure users under customary or usual conditions of use intended by the manufacturer. Although many nail products contain hazardous substances they are allowed on the market because they are not harmful when used as intended.

The FDA does not review or approve cosmetics before they go on the market. However, the agency inspects cosmetic manufacturers and samples and analyzes cosmetics as needed. In the past, the FDA also tracked safety problems through its Cosmetic Voluntary Registration Program (CVRP); this data base collects records of adverse reactions reported to manufacturers as well as reports to the FDA from consumers, doctors, nail technicians, and manufacturers.

While the FDA has the authority to promulgate regulations relating to ingredients, labeling, and packaging (e.g. stability, compatibility, tamper-resistance) of cosmetics, the Commission has the authority to require a special packaging standard for cosmetics under

Section 2(b) of the PPA. The Commission has required child-resistant (CR) packaging for cosmetics in the past. Acetonitrile is found in glue removers for artificial nails, as well as glue removers for cyanoacrylate household glues and certain products used by hobbyists. Because accidental ingestion of acetonitrile was associated with serious personal injury or harm to children less than 5-years-old, the Commission required household glue removers in liquid form containing more than 500 mg acetonitrile in a single container to be placed in CR packaging, effective June 18, 1991 (U.S. CPSC, 1990). In that same Federal Register (FR) notice, the Commission established a special packaging standard for another cosmetic product, home permanent neutralizers in liquid form, containing a) more than 600 mg of sodium bromate or b) more than 50 mg of potassium bromate. A subsequent rule similarly established a special packaging standard for certain mouthwash products containing 3 grams or more ethanol in a single package (U.S. CPSC, 1995).

II. Chemical Information

Methacrylic acid (2-methyl-2-propenoic acid, methyl acrylate, MAA) is a volatile, flammable, colorless liquid with an acrid, repulsive odor. The vapor density is almost 3-times greater than air. The vapor pressure is 68.2 Torr at 20°C. (water = 17.5; ethanol = 40). At temperatures below 16°C., it exists as colorless crystals. The specific gravity is 1.0153 at 20°C (water = 1). It is soluble in most organic solvents (e.g. acetone, alcohol, ether), slightly soluble in cold water (5-9 percent), and somewhat more soluble in warm water (10 percent). It is incompatible with strong alkalis or acids and the liquid is corrosive to metals. MAA is a weak organic acid ($pK_a=4.66$)¹ resembling acetic acid ($pK_a = 4.77$). On the basis of the known pK_a values for acetic acid and MAA, MAA is approximately 1.1-fold stronger than acetic acid in terms of acidity at equal normality². A 10 percent solution has a pH of 2.4. (Lewis, 1993; NLM CHEMID, 1998; NLM HSDB, 1998; The Merck Index, 1997).

The monomer polymerizes easily, especially on heating or in the presence of light, oxidizing agents, or trace amounts of hydrochloric acid. Spontaneous exothermic (heat-generating) polymerization can also occur (Hawley's Condensed Chemical Dictionary, 1987). The monomethyl ether of hydroquinone [100 parts-per-million (ppm)] is characteristically added to prevent polymerization of the monomer. Such MAA solutions are then termed "inhibited." Commercially available grades include 99 percent plus, 98 percent plus (glacial), 85 percent (crude monomer), and 40 percent (aqueous solution) (NLM HSDB, 1998).

¹ pK_a is an equilibrium constant for a chemical reaction, especially for the dissociation of weak acids and other electrolytes. The weaker an acid or base, the larger the pK_a tends to be. Given the concentration and a known value for pK_a , it is possible to calculate the pH of a solution.

² Normality expresses the concentration of a chemical in terms of the molecular weight of that chemical in grams (g) per Liter (L) solution. A 1 Normal (1N) solution of MAA contains 86.1 g/L (8.6 percent); a 1N solution of acetic acid contains 60 g/L (6 percent).

III. Product Information

The major use of MAA in consumer products is as a primer for acrylate-based artificial fingernails. A primer is used to clean, degrease, dehydrate, and etch the nail surface. The primary reason for using MAA is that it is chemically compatible with the acrylate chemicals used to form the artificial nail itself. Both the cosmetology trade literature and scientific literature suggest nail primers are characteristically packaged in small volumes (0.25-2 ounces) at very high (50-99 percent) concentrations. In some cases, manufacturers specify the concentrations of MAA in primers as between 70 and 99 percent. In other cases, manufacturers either list primers as containing greater than 50 percent MAA or do not specify the concentration.

After "priming" the nail, a solution of acrylate monomers, generally ethyl methacrylate in combination with other MAA esters, is applied to the nail (Freeman et al., 1995; Wurdinger, 1996). Polymerization is triggered by addition of a curing agent, with or without a powdery polymeric resin, and the solution is brushed over the natural nail. At least one report in the scientific literature identifies a sculptured nail acrylate preparation containing an unspecified concentration of MAA as one of the acrylate monomers (Fisher, 1980). However, more recent information provided by manufacturers indicates that, due to undesirable cosmetic properties conferred by the MAA monomer, MAA is only present in trace amounts in nail acrylate copolymer preparations (Nail Manufacturers Council, personal communication, 1998).

Staff collected samples of nail products from various sources. The Division of Chemistry (LSC) then analyzed the chemical composition of these products by gas chromatography and mass spectrophotometry (GC/MS), and also measured the pH³ and total free acid [titratable free acidity/alkalinity or titratable acid/alkaline reserve (TAR⁴)].

LSC results are at TAB E. Analysis confirmed the presence of MAA in five samples at concentrations ranging from about 50 to 100 percent. These five samples also yielded values for pH and TAR that were consistent with the presence of concentrated acids capable of severe corrosive activity. The remaining samples, labeled as primers or acrylate copolymer nail preparations, did not contain MAA at detectable levels and did not demonstrate pH or TAR values consistent with the presence of concentrated acids.

³ The term pH refers to a number describing the acidity or alkalinity of an aqueous solution. The pH of a neutral solution is 7.0 at 25°C. Values for pH can range from about 1 for 3 percent hydrochloric acid to 13 for 4 percent sodium hydroxide.

⁴ For acid solutions, the term TAR refers to the total amount of free acidity (hydrogen ion, H₃O⁺) available in a given solution. TAR is measured as the number of milliliters (ml) of a 0.1 M solution of sodium hydroxide required to bring 100 ml of a 1 percent test product to pH 8.0. The TAR of vinegar (4-6 percent acetic acid) is 8.8 ml whereas the TAR of battery acid (35 percent sulfuric acid), a much stronger and more corrosive acid, is 78 ml.

IV. Toxicity

A. Chronic/Subchronic Toxicity

MAA is readily absorbed through mucous membranes of the lungs and gastrointestinal (GI) tract as well as through intact skin. Studies in rats indicate it is rapidly distributed into all major tissues, with the highest concentrations detected in the liver and kidneys (Sapota, 1993). The major routes of excretion are as exhaled CO₂ or as acetyl (carboxyethyl)cysteine derivatives in urine (Delbrussine et al., 1980). Repeated exposure to low levels of MAA via inhalation or ingestion may affect liver and kidney function (Sandmeyer and Kirwin, 1981). Observed effects after 10 days of oral treatment (5-10 mg/kg/day, gavage, rat) included pulmonary congestion and hemorrhage and cloudy swelling of the liver and kidney. Inhalation of 300 ppm (1,050 mg/m³, 6 hours/day for 20 days, rat) resulted in histologically demonstrable renal congestion; 116 ppm (406 mg/m³, 8 hours/day for 180 days, rat) resulted in significant decrease in body fat and disrupted gastrointestinal (GI) function (Gage, 1970).

It is unclear whether MAA is mutagenic. Data in the Salmonella/ mammalian activation plate incorporation assay were negative (Kubinski, 1981). However, MAA was mutagenic in L5178 mouse lymphoma cells at less than 50 micrograms (µg) per ml, producing both breakage and disruption of chromosomes (Moore et al., 1988). MAA also produced chromosomal aberrations in cultured Chinese hamster fibroblasts and micronuclei in mouse bone marrow cells (Sandmeyer and Kirwin, 1981). No data on carcinogenicity is available in humans and data in animals is inadequate to classify MAA as a carcinogen. A limited number of animal studies involving the injection of high concentrations of methacrylates into the rat demonstrated reproductive effects (embryonal-fetal toxicity and teratogenicity).

The long term effects of human exposure to low levels of methacrylates by inhalation or skin absorption are not established (Sandmeyer and Kirwin, 1981; Schwartz et al., 1989). The Occupational Safety and Health Administration (OSHA) and American Conference of Government Industrial Hygienists (ACGIH) respectively recommend a PEL-TLV⁵ and TLV-TWA⁶ of 20 ppm (35 mg/m³) in air (ACGIH, 1992).

⁵ PEL-TWA refers to the permissible exposure limit time weighted average or the time-weighted average concentration for a normal 7 or 8-hour workday and a 40 hour workweek, to which nearly all workers may be repeatedly exposed, day after day, without adverse effect. A PEL has the force of law when promulgated by OSHA.

⁶ TLV-TWA refers to the threshold limit value time weighted average or the time-weighted average concentration for a normal 7 or 8-hour workday and a 40 hour workweek, to which nearly all workers may be repeatedly exposed, day after day, without adverse effect.

B. Acute toxicity

Systemic Toxicity

In animals, reported oral LD₅₀⁷ values range from 277 to 2,260 mg/kg (rat), 280 mg/kg (rabbit), and 827 to 1,600 mg/kg (mouse). The dermal LD₅₀ in the rabbit is 1,243 mg/kg. These reports did not detail the exact cause of death, symptoms, or type of injuries sustained. LC₅₀⁷ values via inhalation are variously reported as 1,350 ppm/4 hours (rat), 3,657 ppm (mouse, details not reported), and 2,522 ppm/1 hour (rabbit). Intravenous administration of 0.1 ml MAA (100 percent) in dogs was lethal. The study in dogs also reported that intravenous administration of smaller amounts increased respiratory rate, decreased heart rate, decreased blood pressure, and produced electrocardiogram changes (Guest et al., 1981; NLM RTECS, 1998; NLM HSDB, 1998; Sandmeyer and Kirwin, 1981).

The above acute animal studies provide little or no detail on specific tissue, organ, or systemic effects associated with lethality, and their utility in predicting acute toxicity in humans is limited (Ayers et al., 1994). Further, little information is available in the medical literature or toxicology data bases concerning the acute systemic effects associated with human exposure to MAA. However, considerable animal and human evidence is available on the effects of MAA following contact with skin, eyes, and mucous membranes.

Sensitization/Irritancy/Corrosivity

Most available animal and human evidence suggests that MAA, in contrast to its esters, is not a strong sensitizer⁸ (Basic Acrylic Monomer Manufacturers Association, 1993; Cosmetic Ingredient Review, 1995; Fisher, 1980; Greim et al., 1995; Parker and Turk, 1983; Savonius et al., 1993).

MAA is an irritant and/or corrosive. Although MAA is classified as a weak acid, it produces the same types of injuries to skin, eyes, and mucous membranes as other acids (acetic, formic, hydrochloric, etc; Cassarette and Doull, 1991; Sax, 1984). Acids tend to produce a destruction of surface epithelium and submucosa with some involvement of blood vessels and lymphatics. Dermal burns can result in mild to severe infections, fixed muscle contractions, osteomyelitis (bone inflammation), and systemic toxicity if acid is absorbed into the blood stream. Inhalation of acid vapors can produce marked nasal irritation, salivation, difficulty breathing, pleuritic chest pain, and bronchospasm. Ingestion generally results in mild to severe oral and esophageal burns. The pyloric end of the stomach can also be severely affected. GI bleeding, perforation, edema, necrosis, stenosis (narrowing of the GI passage), fistulas (abnormal passages or outpocketings), and intestinal injuries can occur. Areas of stricture can develop about 3 weeks post-ingestion.

⁷ In its simplest form, the LD₅₀ or LC₅₀ is the dose of a compound that causes 50 percent mortality in a population of test animals under a discrete set of experimental conditions.

⁸ Under the Federal Hazardous Substances Act (FHSA), a sensitizer is defined as a substance that will induce an immunologically-mediated (allergic) response [16 CFR 1500.3(c)(5)(i)]. A strong sensitizer must meet additional criteria relating to frequency of occurrence and severity of reaction [16 CFR 1500.3(c)(5)(ii-iv)].

Effects of acids on the eye include pain, swelling, corneal erosions, and blindness. It may take 48-72 hours to correctly assess the degree of eye injury. The degree of ocular injury tends to be primarily a function of pH. The corneal epithelium offers some degree of protection against weak acids, but pH levels below 2.5 can be associated with more severe injuries in which the corneal epithelium sloughs and becomes opaque (Parke and Hamill, 1991). Although pH values provide generally accepted guidelines for predicting injury, damage is also to some degree concentration dependent. For example, a 30 second exposure to 0.1 ml of 0.3 percent hydrochloric acid (pH 1.28) has no effect on the rabbit eye. Increasing the concentration of hydrochloric acid to 5 percent results in moderate to severe eye irritation under the same test conditions (Murphy et al., 1982).

Animal Data on Irritancy of MAA

Several sources, notably a recent review from The European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC, 1996) cite specific evidence that MAA, despite classification as a weak acid, can cause severe irritation and/or corrosion on contact with skin, mucous membranes, or eyes in animal models. Draize tests⁹ indicate MAA is a moderate to severe skin irritant. Concentrated MAA (0.5 ml) applied to rabbit skin for periods of 15 minutes to 24 hours caused visible lesions and tissue necrosis at the application site (Guest et al., 1982). In a similar study, 0.5 ml of 99.38 percent MAA resulted in corrosive skin injuries to rabbits at all application sites (Rohm and Haas, 1997). Exposure for periods of 3 minutes, 1 hour, and 4 hours caused similar degrees of injury; also, washing the sites immediately after the period of exposure with a 1 percent soap solution or water alone did not affect outcome. No mortality or clinical signs of systemic toxicity other than skin effects were observed during this study. Dermal application of 1, 5, or 10 ml concentrated MAA also produced severe irritation in guinea pigs (Eastman Kodak, 1979, cited in ECETOC, 1996).

Results from a number of single and repeated exposure inhalation studies demonstrate that MAA is an irritant to the mucous membranes of the respiratory and GI tracts. Concentrations ranging from 1,200 ppm to 2,290 ppm (4.3-8.2 mg/l) caused nasal discharge, gasping, and other respiratory symptoms in rats (Kelly, 1993, cited in ECETOC, 1996). A similar study reported symptoms characteristic of nasal irritancy and histopathological changes in the nasal epithelium in mice (CIIT, 1984, cited in ECETOC, 1996). Severe gastric irritation was observed at autopsy in male albino rats after a single oral gavage of 2 ml MAA (2 g/kg body weight; Rohm and Haas, 1957, cited in ECETOC, 1996).

Severe corneal opacity accompanied by severe injury to the iris and conjunctiva was observed when 0.1 ml undiluted MAA was instilled into one eye of white rabbits for one second, and the eyes were rinsed with 20 ml of lukewarm water 4 seconds after instillation. Effects persisted for at least 7 days (Elf Atochem, 1980, cited in ECETOC, 1996). The ECETOC review concluded that undiluted MAA is corrosive to skin and eyes and, depending on the concentration and time of exposure, MAA can produce skin irritation, ocular and corneal damage, nasal lesions, and irritation to GI mucous membranes in animal models.

⁹ The Draize tests were developed in 1944 to assess eye and skin irritation. Both tests remain in use with some minor variations as standard animal tests.

Draize et al. (1944) also was rated as a moderate irritant, causing corneal opacity, conjunctivitis, and iritis at 24-72 hours with corneal recovery within 7 days and conjunctivitis and iritis persisting for 7 days (Murphy et al., 1982). This degree of injury is not corrosive; corneal opacity and inflammatory changes in the eye and its surrounding mucous membranes are reversible. However, a 10 percent solution of acetic acid, pH 2.28, is severely irritating and may be corrosive depending on the length of exposure and the volume contacting the eyes (Griffith et al., 1980). A severe irritant can cause conjunctivitis, inflammation of the iris, and opacity of the cornea within 24 hours with all injuries persisting for at least 7 days. A corrosive, as noted earlier, can cause irreversible injury.

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). A 4.8 percent solution of MAA has a pH of 2.46, and probably would also be considered a moderate eye irritant. Doubling the MAA concentration to 9.6 percent produces a solution with a pH of 2.3; this solution is a probable severe irritant and possible corrosive on contact with the eyes. 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 (Parke and Hamill, 1991).

MAA may be stronger than acetic acid at equal concentrations with respect to causing irritation or corrosion to human tissues when it is in solution in organic solvents (Encyclopedia of Chemical Safety, 1983, cited in NLM HSDB, 1998). Staff noted previously that 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 (Chieu, 1992; Grant and Schuman, 1993). The limit of solubility of MAA in aqueous solutions is approximately 10 percent in warm water. The concentration of 9.6 percent used in the mouse study required the use of acetone. Any concentration of MAA exceeding 9 percent would have to be placed in solution in acetone or in similar solvents 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, surface area, site affected, and duration of contact. A concentration of approximately 5 percent MAA does not cause serious injury to mouse skin, is not likely to be more than a moderate irritant to eyes of humans or a mild irritant to the skin of humans, and is equivalent to a 4 percent concentration of acetic acid (about the same as vinegar) that is not associated with serious injury or personal 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. Staff is not aware of data defining the precise point between 5 and 10 percent at which injury becomes potentially serious. However, the weight of the evidence indicates solutions containing 5 percent MAA will not cause serious personal harm or illness in young children and leads staff to believe 5 percent is a reasonable level for regulation.

Conclusions

Both the medical literature and toxicological literature document the corrosive effects of MAA. The concentrations of MAA in the primer samples that were examined by staff were very high (50-100 percent). The pH and titratable acid reserve values were approximately 2.3 and 100, respectively, indicating acids capable of severe corrosive activity are contained in the packages. Based on the evidence available at this time, staff believes that household products containing more than 5 percent MAA could present a risk of serious personal injury or illness to children less than 5-years-old resulting from their handling, use, or ingestion.

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TAB B



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

MEMORANDUM

DATE: AUG 12 1998

TO : Mary Ann Danello, Ph.D., Associate Executive Director, Directorate
for Epidemiology and Health Sciences (EH)

THROUGH : Marilyn L. Wind, Ph.D., Director, Division of Health Sciences *MW*
Susar Ahmed, Ph.D., Director, Division of Hazard Analysis *SA*

FROM : Susar C. Aitken, Ph.D., Pharmacologist, Division of Health Sciences *SA*

SUBJECT : Human Injuries from Nail Primers Containing Methacrylic Acid

HUMAN INJURIES FROM NAIL PRIMERS CONTAINING METHACRYLIC ACID

Introduction

This memorandum addresses human injuries associated with exposures to nail primers containing methacrylic acid (MAA). Staff analyze and discuss the available evidence contained in human injury data bases and the medical literature, focusing on the degree of injury and means of access. Emphasis is placed on injuries to children less than 5-years-old.

Discussion

A. AAPCC Injury Data

The American Association of Poison Control Centers (AAPCC) collects reports made to participating poison control centers within the United States of exposures to toxic chemicals (drugs, household products, poisonous plants, etc.) in the Toxic Exposure Surveillance System (TESS). The poison control centers serve approximately 85 percent of the U.S. population, but data do not represent a probability sample.

AAPCC Case Reports

The AAPCC provided 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. Details on the more significant cases from the collection follow below.

In an incident coded as having a major medical outcome (1997) and the only incident reported outside the home, 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. During this period, she received acetaminophen for pain and antibiotic ointment to prevent infection of the blisters on her lips. Blisters on her cheeks were open. On the third day, she was transferred to a regular bed and her cheek blisters had healed sufficiently to allow treatment with antibiotic ointment. An endoscopy on day 4 revealed no gastrointestinal (GI) burns, and she was discharged on day 5.

A 1-1/2 year-old female experienced burns over half her chest after spilling a bottle of primer on herself. The child experienced immediate pain, began screaming, and, on the advice of a poison control center specialist, was taken by her parents to the ER. She was treated for first degree burns and released later

that evening. 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 2-year-old female spilled some primer on her abdomen. Although washed immediately, medical evaluation confirmed a 4-square-inch second degree burn. The burn healed without complications.

Two other children splashed nail primers in or near their eyes. In both cases, the parent washed the eyes and face extremely thoroughly, and then took the child to their personal physician. Neither child experienced serious injury.

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 local poison control center advised taking the child to an ER, where she was treated for first degree burns and released the same day. However, the pain persisted several days and the burns did not begin to resolve for another week. The primary physician recommended consultation with a plastic surgeon. However, the burns eventually did heal without scarring. According to the AAPCC record, this incident is coded as having a moderate outcome.

Five other children less than 5-years-old attempted to ingest primers. Although none experienced severe injury, all experienced pain and blistering around the mouth. Two children were taken to an ER to determine whether an ingestion actually occurred, and were treated and released. The other three children were treated in the home.

Compiled TESS Data

The staff analyzed the compiled TESS data isolating nail products containing MAA for the years 1996 and 1997. Children less than 5-years-old were involved in 467 reports, including 341 poisonings (ingestion, ingestion/dermal), 11 ocular exposures, and 115 dermal exposures. No deaths were reported. One poisoning with major¹ medical consequences was reported in 1997. This incident was discussed previously in the case reports. Thirty-two poisoning outcomes were coded as moderate (10.7 percent) and 137 poisonings (39.3 percent) were coded as minor. The remaining poisonings included those with no effects or unrelated

¹ Minor Symptoms - The patient exhibited some minimal signs or symptoms which resolved rapidly.
Moderate Symptoms - 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 the patient returned to a pre-exposure state of well-being with no residual disability or disfigurement.
Major Symptoms - The patient exhibited some symptoms which were life-threatening or resulted in disfigurement or residual disability.

effects, incidents that were not followed but were expected to be non-toxic or minor, and 10 incidents that were coded as not followed but, in the judgment of the coder, may have had toxic effects. Approximately 90 percent of calls reported an exposure in the home (either the child's or someone else's personal residence).

B. CPSC Injury Data

Staff examined CPSC records from several available data bases, including the National Electronic Injury Surveillance System (NEISS, January, 1988 - March 31, 1998), the Injury and Potential Injury Incident data base (IPII January, 1980 - March 31, 1998), the In-Depth Investigations data base (INDP, January, 1980 - March 31, 1998), the Death Certificate data base (DTHS, January, 1980 - March 31, 1998), and the Children and Poisonings data base (CAP, January, 1978 - December, 1987). NEISS is a nationally representative stratified probability sample of emergency room (ER) hospitals within the United States and its territories. IPII is a compilation of incidents reported in letters, hot line complaints, medical examiners' and coroners' reports (MECAP), and newsclips. The DTHS data base contains death certificates purchased according to certain external causes of death (Ecodes) likely to be associated with consumer products from all states, New York City, and the District of Columbia. INDP files compile additional injury details through investigations conducted by telephone or on site in response to information obtained from the other CPSC data bases. The CAP data base contains all NEISS reports of poisonings to children less than 5-years-old received since 1978. Additional variables relating to products involved in these incidents are coded in this data base.

Nail primers are available in several formulations, but only MAA-containing nail primers that are used as nail bonding agents can inflict potentially serious burns on immediate contact with skin, eyes, or mucous membranes. Staff has determined that all other cosmetic products termed nail primers are mild to moderate irritants, and do not present the corrosive hazard of MAA. Staff therefore assumed that, when formulation was not specifically identified, the causal agent in a serious injury due to nail primers was MAA.

In-Depth Investigations/Case Reports

In-Depth Investigations (IDIs) conducted by CPSC staff provided details on several injuries due to nail primers believed to contain MAA. The records for the cases described below indicate that victims suffered immediate intense pain and incurred serious burns, strongly suggesting exposure to MAA.

A 2-year-old female accessed 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 1-1/2 to 2 ounces on her thigh. After trying to rub it off with her hand she then rubbed her face. She was quickly rinsed off in a

shower and taken to the ER. She was treated and released. She 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.

An 18-month-old male ingested a nail bonding agent (primer). He suffered burns of the mouth and throat. The child was treated and released at a local hospital. No further details were available.

A 2-year-old male accessed an artificial nail kit left on a living room table. The child was about to ingest the bonding agent (primer) from its container when he spilled about 1-1/2 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 an ER where his burns were treated and an undetermined substance was administered orally. He remained in the hospital under observation for two nights, and was then transferred to another hospital for an endoscopy because he was having difficulty swallowing. He 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 spilled about 1 ounce of the primer on his hand. He then rubbed his mouth with his hand and began drooling and frothing. He was immediately taken to the hospital, the chemical burns that he received from the spill were treated, and he was released the same day.

The address and phone number of the family involved in another investigation assignment, originating from a 1995 report in NEISS, could not be verified. However, staff obtained the hospital records. In this case, a 2-year-old male was hospitalized after accessing a bottle of nail primer. The child spilled approximately 1 milliliter (ml) on his abdomen and left thigh. The ER staff saw no evidence that he swallowed any of the product (no drooling, mouth odor, or mouth burns). The injuries were diagnosed as second degree burns and he was admitted for observation. He was discharged the next day.

Compiled CPSC NEISS Data

Nail products specifically identified as primers or as containing MAA were cited in 85 case records (84 in NEISS, one in IPH) between January 1, 1988 and September 30, 1998². Records in NEISS are coded and descriptive case reports

² The number of actual reports of ER visits due to nail primers containing MAA is not certain. Some NEISS reports did not provide sufficient detail to conclude that the nail primer implicated in a specific exposure contained MAA. It is also possible that the total of 395 incidents reported to involve other nail products could include some additional injuries due to MAA-containing nail primers. In addition, the data relating to cosmetic products, including nail primers, are not available for the period between January, 1994 and November 10, 1994 due to coding changes affecting NEISS data collection.

that can yield national estimates of injuries treated in emergency rooms when a sufficient number of incidents are entered into the data base³. Since all injuries are not treated in emergency rooms, NEISS estimates provide a lower bound for injuries involving specific household products. NEISS estimates can also provide information on the patterns of exposures to specific household products (severity, site, type of injury inflicted, etc.). 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. Data are shown in TABLE 1. An estimated $2,723 \pm 967$ ER visits due to exposures to nail primers occurred between January 1988 and September 1998. The lower and upper 95 percent confidence limits were approximately 1,756 and 3,690 respectively. The home was the location of injury in at least 83 percent of estimated ER visits (2,272). Hospitalization was necessary in approximately 10 percent of estimated ER visits (262). As noted previously, nail primers are available in several formulations, but only MAA-containing nail primers are known to be capable of causing immediate symptoms (pain and burns) likely to precipitate ER visits and require hospitalization.

C. CVRP Data Base

The Food and Drug Administration (FDA) maintained a data base known as the Cosmetic Voluntary Registration Program (CVRP) until the Spring of 1998. The CVRP collects records of adverse reactions reported to manufacturers and reports to the FDA from consumers, doctors, nail technicians, and manufacturers. As implied by its name, all records are voluntary reports. The CVRP data base contained four reports of injuries from nail primers. 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). An adult also reported that a primer spilled on her legs at a nail salon caused permanent scars (1992). An adult reported that a nail product containing MAA ate through her acrylic nail and natural nail into the flesh of her fingertip (1993). Another adult reported that an acrylic nail primer burned and blistered the skin surrounding the nail (1988).

D. Medical Literature

Two recent articles in the medical literature document the toxicity of MAA as a corrosive. Both articles concerned nail care products, notably primers, and accidental injuries to young children. One article focused on medical case reports (Linden et al., 1998). The second article focused on analysis of data contained in the NEISS and TESS data bases (Wolff and Shaw, 1998).

³ The number of NEISS reports of injuries due to nail primers was less than 20 per year. Staff do not ordinarily use fewer than 20 annual reports of injuries to obtain annual estimates; the data in this case were pooled to obtain an 11-year estimate.

Medical Literature Case Reports

Linden et al. (1998) reviewed the hazard of nail care products, among them nail primers containing MAA, and reported the medical consequences of oral 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 ER of a local hospital observed that the child was in great distress on arrival 30 minutes post-ingestion. He required endotracheal intubation to maintain the airway and upper GI tract 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 hospital discharge 28 days post-admission. 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.

The second case involved a 2-1/2-year-old male who 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 copious rinsing of his body and the application of silver sulfadiazene and aloe to burn areas. All burn areas healed without scarring.

In the third case report, 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. One of the accelerators was n,n-dimethyl-p-toluidine (DMT). The woman arrived at the ER 30 minutes post-ingestion with symptoms of lethargy and cyanosis. Administration of methylene blue one hour after arrival corrected the methemoglobinemia⁴ and cyanosis associated with ingestion of DMT. However, lesions of the pharynx were also noted, and GI endoscopy, 12 hours post-ingestion, revealed 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. The corrosive injuries were almost certainly due to the MAA. Although DMT, methylethyl ketone, and ethyl methacrylate are mild to moderate irritants, these chemicals are not corrosives.

⁴ Methemoglobin is a compound formed from hemoglobin by oxidation of iron from a ferrous form to a ferric form. In its ferric form, hemoglobin cannot function reversibly as an oxygen carrier, cells are deprived of oxygen, and cyanosis, a bluish coloration of skin and mucous membranes, develops.

NEISS and TESS Data Bases (Medical Literature)

Wolff et al. (1988) identified 759 reports of exposures to MAA-containing nail products occurring from 1993 through 1995 in the TESS data base. These data were collected retrospectively by AAPCC staff through examining text details in individual case reports. The CPSC staff ordinarily do not have access to individual case records collected by the AAPCC, and can only discuss the data as compiled and presented in this article. Children less than 6-years-old accounted for 564 exposures. Most of the exposures to children less than 6-years-old occurred in the home and involved mixed dermal/ingestion or ingestion scenarios. Two-year-old children were most at risk (approximately 330 exposures). Approximately 10 percent of young children suffered moderate to major injuries. The data did not show concentration-related differences in severity of injuries at concentrations of MAA ranging from 70 to 100 percent, suggesting the potential for injury at these high concentrations was identical.

The authors also analyzed the above data using a product hazard score as described by Litovitz and Manoguerra (1992) for poisonings to children less than 6-years-old. While several variables, including acute toxicity, availability, access, formulation, packaging, and child-resistant closure use can affect hazard, the product hazard score is calculated solely on the basis of observed injury data. The exposures to a given product with major or fatal outcomes are summed and divided by the total number of exposures to that product. The raw hazard score for the entire TESS data set of poisonings to children less than 6-years-old (1993-1995) was 0.00062. The normalized hazard score for all poisonings of children less than 6-years old is $0.00062/0.00062$ or 1. The raw hazard score for MAA-containing nail primers was 0.0053. The final normalized hazard score for MAA-containing nail primers was $0.0053/0.00062$ or 8.6. The authors compared the MAA normalized hazard score with the normalized hazard scores reported by Litovitz and Manoguerra for other products during the period 1985-1989. The raw hazard factor for the entire data base (1985-1989) was also 0.00062, identical with the score for 1993-1995. The normalized hazard scores for MAA-containing primers of 8.6 was virtually the same as nutritional supplements containing iron (8.5) and much higher than cosmetics as a group (0.2).

This article also summarized NEISS data (sample counts) collected between 1991 and 1993 relating to nail products. A total of 421 ER visits for children less than 6-years-old were reported involving exposures to nail products. Artificial fingernail primers were implicated in 28 of the ER visits by children less than 6-years-old. Most exposures involving preschool children less than 3-years-old (25/28) occurred in the home, and caused dermal burns (21/28). However, attempted ingestions were suspected in most of the 28 incidents. In order to correlate NEISS injury severity scoring with TESS injury data, the authors recategorized NEISS data. Scores of 1 (mild injury to small area) through 3

(moderate injury to somewhat larger area) were combined as no effect/minor, and scores of 4 (moderate injury to still larger area) through 7 (hospitalized poisoning) were combined as moderate/major. Severities of all types of injuries from nail primers were more often rated as moderate to major (20/32; 62.5 percent) than injuries from other nail products (120/737; 16.3 percent). For injuries specifically causing dermal burns, primers were again frequently rated as moderate to major in severity (16/21; 76.2 percent).

The authors acknowledged the limitations of their report. Such difficulties as chronologically overlapping data sets, failure to identify chemical content in NEISS, failure to identify specific product names in both NEISS and AAPCC reports, etc., only permitted an incomplete sampling and analysis of available data.

Conclusions

Based on the number of incidents reported to the AAPCC, there were at least 233 exposures to nail primers containing MAA per year (children less than 5-years-old) during 1996 and 1997, and a minimum of 188 exposures (children less than 6-years-old) per year during the years 1993 through 1995. NEISS data agree well with the above TESS data, suggesting an estimated 160 to 335 children visit hospital ERs annually following exposure to various formulations of nail primers. These nail primers can contain methacrylic acid and the data suggest nail primer formulations containing MAA are more frequently involved in serious injuries that can require hospitalization. In spite of differences in the reporting mechanism for NEISS and TESS data bases, both sets of data indicate approximately 80 to 90 percent of exposures of young children occur in the home, and approximately 10 percent of exposed children incur serious injury. The case details reported in AAPCC and INDP records and in the medical literature further confirm that nail primers containing MAA cause serious personal injury or illness to children less than 5-years-old. Access of young children to these products in their homes results in serious burns to skin, eyes, and mucous membranes of the GI tract.

References

- Linden, C.H., R.P. Dowsett, D.W. Scudder, E.L. Liebelt, and A. Wolff (1998). In Press. Another Hazard of Fingernail Products: Corrosive Injury from Methacrylic Acid in Nail Primers.
- Litovitz, T., and A. Manoguerra (1992). *Pediatrics* 89:999-1005. Comparison of Pediatric Poisoning Hazards: An Analysis of 3.8 Million Exposure Incidents.
- Wolff, A., and J. Shaw (1998). *Arch. Pediatr. Adolesc. Med.* 152:41-46. Childhood Injuries from Artificial Nail Primer Cosmetic Products.

TABLE 1. ESTIMATES OF EMERGENCY ROOM VISITS DUE TO EXPOSURES TO NAIL PRIMERS

(NEISS Data, January 1, 1988 - September 30, 1998)
(Children less than 5-years-old)

	Estimate	# of Incidents	Margin of Error	95% Confidence Interval	
				(lower)	(upper)
DISPOSITION					
Treated & Released	2,461	71	902	1,559	3,364
Hospitalized/ Transferred	262	13	x	x	x
LOCATION					
Home	2,272	63	855	1,417	3,126
Other/Unknown	451	21	x	x	x
TOTAL	2,723	84	967	1,756	3,690

Generalized standard errors were used to calculate estimates and associated 95 percent confidence intervals as documented in *National Electronic Injury Surveillance System (NEISS) Estimated Generalized Relative Sampling Errors*, Kessler, E., and Schroeder, T., CPSC, 1997. The estimates are based on the 72 cases identified in NEISS under product codes 5555 (poisoning or burn to children less than 5-years-old involving a product for which there is no current product code), 2630 (nail preparations), and 2631 (nail hardeners) and an additional 12 cases identified under various other codes. Zero-weighted cases are not part of the probability sample used to compute national estimates. Therefore, not every incident contributed to the estimates. Records were compiled for the years 1988 through 1998, and estimates were adjusted to account for changes in the NEISS samples and frames in 1990, 1991, 1994, and 1997. Standard errors are not ordinarily presented when estimates are less than 1,200; therefore, these standard errors are not shown for the "hospitalized" and "other/unknown location" categories.

TAB C



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

MEMORANDUM

DATE: 17 AUG 1998

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

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

FROM : Marcia P. Robins, ^{MPR}EC

SUBJECT: Economic Considerations: Proposal to Require Child-Resistant Packaging for Household Products Containing Methacrylic Acid

The Directorate for Economic Analysis reviewed the economic, small business and environmental effects of the subject proposal. Attached are the findings of these reviews.

Attachment(s)

**Economic Considerations: Proposal to Require
Child-Resistant Packaging for Household Products
Containing Methacrylic Acid**

The Consumer Product Safety Commission (CPSC) enforces the Poison Prevention Packaging Act (PPPA) of 1970, which authorizes standards for special or child-resistant (CR) packaging to protect children under age five from serious personal injury or serious illness resulting from handling, using, or ingesting hazardous household substances. Commission staff recently reviewed a study on childhood injuries from primers containing methacrylic acid.¹ These primers are used in cosmetic fingernail enhancement preparations. Staff of the Directorate for Epidemiology and Health Sciences (EH) evaluated the toxicity and human injury data and concluded that exposure to methacrylic acid results in serious personal injury and illness. As a result of the review and analysis, the EH staff recommended that the Commission require special packaging for household products containing more than 5 percent methacrylic acid in a single package.

The Food and Drug Administration (FDA) regulates nail enhancement products for both home and salon use under the Federal Food, Drug, and Cosmetic Act. Nail products sold as cosmetics, must be free of poisonous or deleterious substances that might injure users under the usual or customary conditions of use intended by the manufacturer. Thus, primers containing methacrylic acid are allowed in the market by FDA because they are not harmful when used as intended.² Child-resistant packaging requirements are currently in effect for other cosmetic products including artificial finger nail glue removers containing acetonitrile and permanent wave neutralizers containing sodium bromate or potassium bromate.

This report presents a summary of information available from manufacturers, trade association representatives, journal articles, and the trade press.

OVERVIEW

Methacrylic acid is frequently used as a primer for nail enhancement procedures involving acrylic nail overlays. The overlays can be used to hide imperfections or lengthen the appearance of the nail. The acrylic mixture (a gel or a combination of a liquid monomer, a powdered polymer, and an accelerator) is sculptured or formed on the natural nail.

¹Memo from Susan Aitken, Ph.D. "Toxicity of Methacrylic Acid" (August, 1998).

²FDA Consumer, December 1995.

Nail primers are used to help the acrylic overlays adhere to the nail surface. The nail surface and the acrylic are both smooth surfaces that do not naturally stick together well. According to an industry spokesperson, methacrylic acid primers act like a double-sided tape, increasing the compatibility of the nail plate and the enhancement product. Methacrylic acid primers are corrosive and are typically marketed for professional use. Some primers are 100 percent methacrylic acid; others contain ingredients that lessen its corrosiveness, affect how it dries on the nail, and help maintain shelf life.³

MARKET INFORMATION

Trade Association Representation

Nail primers are marketed by two separate industry groups. Primers which are primarily for use by professional nail technicians are represented by the Nail Manufacturers Council (NMC). Many of the primers supplied by member companies contain methacrylic acid and are labeled "For Professional Use Only". These primers are typically distributed through wholesale distributors directly to nail salons and to retail beauty supply stores. Some retail beauty supply stores sell only to licensed professionals. Others sell to professionals and consumers alike.

Distributors of primers specifically marketed to consumers are represented by the Cosmetic, Toiletry, and Fragrance Association (CTFA). According to an association spokesperson, an informal survey of its membership and some of its internal committees indicated CTFA member companies do not use methacrylic acid in nail primers.

Packaging and Prices

Although methacrylic acid primers are typically labeled *For Professional Use Only*, staff visited several local retail stores, including beauty supply retailers, and purchased eight samples of liquid nail primers. Store personnel did not ask for proof of professional licensing (i.e., state license number). Staff is unaware of any laws prohibiting the sales to the general public of products intended for use by licensed beauty professionals.

The primers were labeled to contain methacrylic acid or a derivative. However, analysis by the EH Division of Chemistry confirmed only four of the samples contained detectable amounts of methacrylic acid. The primers were packaged in small bottles containing 1/4 oz to 1/2 oz primer. All were sold individually packaged; none were CR and seven of the eight were labeled *Professional Use Only*. Six primers had continuous turn (CT) plastic closures with an applicator brush attached at the inside

³NAILS, February 1995.

center of the closure. Two primers had CT closures without attached brushes and were packaged inside paperboard cartons; a separate brush was included with one of these products. Retail prices for 1/4 oz primer ranged from \$3.19 to \$6.75. The 1/2 oz primers were priced at \$3.27 to \$12.95.

One additional liquid primer, labeled *For Professional Use Only* and advertised in the trade press, was obtained by staff through mail order purchase. Laboratory analysis confirmed the presence of methacrylic acid in this sample. It came in a nonCR bottle with a CT closure and an attached brush priced at \$5.99 for 1 oz and \$7.94 for 2 oz. Some methacrylic acid primers are sold in felt tip marker style packages. Thus, one was also purchased through mail order. However, staff could not confirm that this sample contained methacrylic acid.

The package labeling on methacrylic acid nail primers includes warning statements such as: *FOR PROFESSIONAL USE ONLY. WARNING: CORROSIVE MIXTURE. CAUSES BURNS. Harmful or fatal if swallowed. Keep away from eyes. Avoid any contact with skin. Use only in well ventilated area. KEEP AWAY FROM CHILDREN! USE AT YOUR OWN RISK.*

According to industry representatives, more than 95 percent of methacrylic acid primers are supplied in 1/4 and 1/2 oz bottles; the remainder is supplied in bottles of up to 2 oz. The larger bottles are probably used to refill smaller bottles. The small package size minimizes the amount of primer that can be accidentally spilled by the nail technician while the product is in use. It also limits the amount of primer that can become contaminated by nail filings that are carried, by the brush, from the nail to the bottle.

Suppliers and Sales

One industry source said there are about 20-25 suppliers of methacrylic acid primers. However, another source said that most suppliers of acrylic nail overlay products also market a primer. If so, there may be as many as 50 nail primer suppliers. The primer is purchased in bulk by the supplier and repackaged into small bottles. An estimated 90 percent of primers marketed to professionals contain methacrylic acid.

Based on available data sources, staff identified 13 companies that market methacrylic acid-containing nail primers. The Standard Industrial Classification (SIC) codes for these establishments includes Perfumes, Cosmetics, and other Toilet Preparations (SIC 2844); Service Establishment Equipment and Supplies (SIC 8087); Miscellaneous Retail Stores (SIC 5999). Two beauty shops (SIC 7231) were also listed among the 13 marketers of methacrylic acid primers. However, it is unlikely that many beauty shops or nail salons sell primers; instead they sell the nail enhancement services in which primers are used.

The Small Business Administration (SBA) sets size standards for various industries using either annual receipts or number of employees. Firms classified under SIC 5087 must have fewer than 100 employees, firms classified under SIC 2844 must have fewer than 500 employees, and firms classified under SIC 5999 and 7231 must have sales of less than \$3.5 million annually. Additionally, to be considered a 'small business' by the SBA, a business must be independently owned and operated and not dominant in its field of operation. Employment and sales volume information was obtained for 9 of the 13 companies identified by staff.⁴ Based on SBA criteria 7 of the 9 companies are considered 'small businesses'.

There are no generally available sales estimates for nail primers nor are there firm estimates of market share. One industry spokesperson reported that the leading supplier of methacrylic acid-containing primers accounts for at least 50 percent of the market and that four additional manufacturers share about 35-40 percent of the market. However, another source estimated the market share of the 5 leading suppliers at 50-60 percent and includes a slightly different list of suppliers.

Using industry estimates on primer usage by nail technicians, staff preliminarily estimates annual unit sales of methacrylic-acid containing primer at about 1.0-1.3 million units in 1/4 oz, 1/2 oz, and larger size units.⁵ The annual retail value of these units, based on prices in the local area per 1/4 oz (\$4-5) amounts to \$4-\$6.5 million. The wholesale value of these products is about \$2.9-\$4.6 million based on a 40 percent mark-up that is typical in the industry.

Spokespersons for the industry are unable to estimate the number of consumers that may be using methacrylic acid-containing primers at home.

EFFECTS OF THE PROPOSED RULE ON SMALL BUSINESSES

According to NMC, the professional nail preparation supply industry is dominated by small businesses. At a meeting with CPSC staff, representatives of the NMC commented that member companies have considered voluntarily using CR packaging for primers containing methacrylic acid, but, as a group, have not as yet found a packaging supplier. They noted that many marketers use similar packaging, i.e., 1/4 oz glass bottles.

According to EH staff, the technology exists to produce CR packaging suitable for use with methacrylic acid-containing nail primers. There are at least two U.S. based packaging

⁴American Business Credit (1997)

⁵NAILS 1997-1998 FactBook.

manufacturers that could possibly develop CR closures with applicator brushes. Such packaging could be developed in about one year. In addition, a European packaging manufacturer is interested in testing a package design using PPPA protocols. The design was developed for products packaged in tubes but may be suitable for small packages containing primer. Another possible package, is a felt tip marker pen currently being used for a methacrylic acid-containing primer sold through a beauty supply mail order catalog. No information is available at this time regarding the incremental cost of appropriate packaging.⁶

While a proposal to require special packaging for methacrylic acid-containing products may affect many small suppliers, the magnitude of the impact on any individual supplier is expected to be minimal. Typically, incremental costs for CR packaging have been low relative to the retail cost of the product for which they are used. Incremental costs for special packaging would most likely be passed on to users (professional nail technicians and consumers who purchase professional-use primers). Thus, based on currently available information, there is not likely to be a substantial effect on a significant number of small businesses.

In order to obtain more complete information about all the companies and their methacrylic acid-containing products, the draft Notice of Proposed Rulemaking requests that suppliers, especially small businesses and organizations representing small businesses, provide specific information about their products and the effect the proposed rule would have on them.

EFFECTS OF THE PROPOSED RULE ON CONSUMERS

Commissioner data indicate that young children are being exposed to products in the home that are labeled for professional use only but are available for purchase by consumers and that these exposures have resulted in injuries from ingestion and dermal burns. Consumers would benefit from a requirement for CR packaging of methacrylic acid-containing nail primers in that the products of all marketers would be packaged to reduce the potential for accidental ingestions by young children. These benefits would extend to all methacrylic acid-containing products including those labeled 'For Professional Use Only' that consumers are able to purchase for use in their own homes.

⁶Memo from T. Asebe, EH, to S. Aitken, EH, dated ----1998.

Preliminary Environmental Assessment of Proposal
to Require Child-Resistant Packaging for Household Products
Containing Methacrylic Acid

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 preliminarily assessed the possible environmental effects association with the proposed Poison Prevention Packaging Act (PPPA) packaging requirements for household products containing methacrylic acid.

The Commission's regulations at 16 CFR Sec. 1021.5 (c) (3) state that the rules requiring special packaging for consumer products normally have little or no potential for affecting the human environment. Preliminary analysis of the impact of this proposed rule indicates that child-resistant (CR) packaging requirements for the production of marketers of methacrylic acid-containing products under the proposed rule will have no significant effects on the environment. The manufacture, use, and disposal of CR closures will present the same environmental effects as do non CR closures.

TAB D



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

MEMORANDUM

DATE: August 25, 1998

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

Through: Mary Ann Danello, Ph.D., Associate Executive Director for Epidemiology and Health Sciences *mad*
Marilyn L. Wind, Ph.D., Director, Division of Health Sciences, Directorate for *mdw* Epidemiology and Health Sciences

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

SUBJECT: Technical Feasibility, Practicability, and Appropriateness Determination for Methacrylic Acid Containing Products to Require Child-Resistant Packaging (CRP).

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 methacrylic acid containing products, the Commission needs to make the finding that CR packaging is technically feasible, practicable, and appropriate for methacrylic acid containing 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 evaluated by the staff. All of these products are currently packaged in non-child-resistant (NCR) packaging¹. Laboratory tests conducted by the Division of Chemistry (LSC) confirmed that five out of ten samples contain methacrylic acid. The methacrylic acid containing products are packaged in 0.25 to 2 ounce (oz) bottles with 13 to 20 millimeter (mm) non-child-resistant-continuous-threaded (NCRCT) plastic closures. 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 may also contain methacrylic acid⁴. This product is packaged in a plastic marker type packaging⁸. The package looks like a pen with a marker type tip (moistened fiber applicator tip). The applicator tip is overcapped with a NCR overcap. We have child protocol data (no senior data) for an ASTM Type IIA (lug finish), 16 mm outer diameter package that might be redesigned and used for the plastic marker type packaging¹¹. The descriptions of these six packages 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	Yes, built-in	2	clear, brown	glass	No
20	NCRCT	Plastic	No	Yes, built-in	0.25	clear, brown	glass	No
15	NCRCT	Plastic	Yes, 27	Yes, separate	0.5	clear	glass	Yes, Black
13	NCRCT	Plastic	Yes, 27	Yes, built-in	0.25	clear	plastic	Yes, Black
13	NCRCT	Plastic	No	No	0.5	clear	glass	Yes, Purple
10	NCR-SNAP CAP	Plastic	Yes, 57	Built-in marker tip	0.07 (2 g)	white	plastic	No

Recently, the staff met with the American Beauty Association and other nail care product manufacturers. 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 burned 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 ASTM² Type IA cap with a built-in inside insert for applicator brush³. 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 bottle⁶. This manufacturer is also supplying 20 mm NCRCT packaging with a built-in applicator brush for methacrylic acid containing products. This manufacturer can produce a 20 mm CR ASTM Type IA packaging with a built-in applicator brush⁴. Another CR packaging manufacturer makes a CR cap with a 20 mm ASTM Type IA dropper⁵. Examination of this 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 cap developed for products packaged in tubes⁶. 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, we do not have any protocol data for this package.

Based on available information, the staff believes that data supports 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 brushes⁴. Most manufacturers are very small companies and they use manual filling lines⁴. 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 (please see Table 1) are already packaged with 20 mm finish packages. If necessary, a plastic plug-in insert can also be used to decrease the inside diameter of a bottle¹⁰. 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 methacrylic acid containing primer is currently using such a design to package its product.

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 packages⁴. 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 products⁹.

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 brushes 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 9 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. The staff are not aware of CR packages with built-in applicator brushes on the market for this product. 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. Companies that might have problems in meeting the effective date could request a temporary stay of

enforcement. Therefore, an effective date of one year is recommended.

Conclusion

The staff concludes that data support the findings 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.

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