METHACRYLATE PRODUCERS ASSOCIATION, INC. 17260 Vannes Court, Hamilton, VA 20158 Office: (540) 751-2093 • Fax: (540) 751-2094 • e.hunt@comcast.net

THE METHACRYLATE PRODUCERS ASSOCIATION'S POSITION ON USE OF METHACRYLIC ACID AND UNREACTED METHACRYLATE MONOMERS LIQUID FORM IN ARTIFICIAL NAIL PRODUCTS

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The Methacrylate Producers Association, Inc. (MPA) believes that methacrylic acid (MAA) and its esters (including methyl methacrylate (MMA), ethyl methacrylate (EMA), n-butyl methacrylate (nBMA), isobutyl methacrylate (iBMA), and 2-ethylhexyl methacrylate (2EHMA)) in unreacted monomeric liquid form are not appropriate for use in artificial nail products. The corrosive properties of the acid and skin sensitization properties of the esters, reflected in past reports of injury due to their use in some nail products, indicate their use in such products should be restricted.

MPA is an association of U.S. manufacturers of MAA and - its esters, whose members include Evonik Cyro LLC, Arkema Inc., Lucite International, and The Dow Chemical Company. MPA and its members have product stewardship programs to support appropriate use of the chemicals they market. For many years, MPA members have recommended that - MAA and its esters in their unreacted monomeric liquid form should not be used in artificial nail products.

Public and Governmental Concern

The hazards of unreacted MMA monomer use in cosmetic nail products have been known for decades. The Food and Drug Administration (FDA) seized numerous MMA-containing nail products in the 1970s, after investigating reports that MMA caused fingernail damage and deformity. FDA has warned against the use of MMA in artificial nail products ever since.

For example, in its 1989 Cosmetic Handbook, FDA specifically cautioned:

Nail builders (elongators, extenders) have been involved in numerous reports of irritation, inflammation and infection of nail bed and nail fold as well as complaints of discoloration, splitting, and loss of fingernails . . . The methacrylate monomers currently used in nail builders are mostly ethyl, hydroxyethyl, butyl, isobutyl, hydroxypropyl or other esters of methacrylic acid. Methyl methacrylate is now rarely used <u>The currently used esters of methacrylate</u>.¹

FDA continues to highlight the dangers of use of unreacted - MMA monomer in product safety advisories for nail care products available on its website. FDA notes that such use can result in adverse reactions "such as redness, swelling, and pain in the nail bed."² And despite its 1989 assessment that - MMA is "now rarely used," FDA states that - MMA "may still be found in some artificial nail products."³ Articles in the beauty salon trade press and national media have also detailed adverse reactions caused by the chemical.

At least 32 states prohibit the use of MMA in nail salons. (See the attached chart.) In some states that have not enacted MMA prohibitions, state cosmetology boards have instituted their own prohibitions. Examples include the West Virginia State Board of Barbers and Cosmetologists,⁴ the Pennsylvania State Board,⁵ and the Oregon Occupational Safety and Health Division.⁶

With nail salon use of MMA prohibited in so many states, MPA is concerned that other unreacted methacrylate monomers, such as EMA, may be substituted in cosmetic products. FDA notes that EMA monomer is "commonly used today in acrylic nails." However, FDA draws no distinction between MMA and EMA

Product and Ingredient Safety/Product Information/ucm 127068. htm.

¹ FDA, COSMETIC HANDBOOK 27-28 (1989) (emphasis added).

² FDA, Product Safety Information for Nail Care Products, available at http://www.fda.gov/Cosmetics/

³ Id.

⁴ *See* West Virginia State Board of Barbers and Cosmetologists, *Consumer Information, available at* http://www.wvbbc.com/MenuStructure/GeneralInformation/GeneralInformation/ConsumerInformation/tabid/1548/ Default.aspx.

⁵ See State Disciplines Applicant, 7 Licensed Professionals, Lancaster Intelligencer Journal, April 4, 2011; Pennsylvania State Board of Cosmetology, Salon Licensure Application, available at

http://www.portal.state.pa.us/portal/server.pt/document/487659/cosmetology_-_salon_licensure_application_pdf? qid=03253195&rank=2;

⁶ See Oregon OSHA, Safety and Health Hazards in Nail Salons, available at www.orosha.org/pdf/pubs/fact_sheets/ fs28.pdf

when noting that adverse reactions can result from "reactive monomer" use."⁷ The MPA supports the FDA position that adverse reactions can result from unreacted methacrylate monomers, and for this reason MPA does not support use of other unreacted methacrylate monomers in artificial nail products.

MPA has provided information to FDA and the Consumer Product Safety Commission (CPSC) on this subject. MPA supported the CPSC's issuance of a requirement that consumer nail products containing MAA be packaged in childresistant containers. And it has urged FDA to restrict cosmetic use of MAA and methacrylate monomers in their unreacted liquid form.

MPA's Petition to the Cosmetic Ingredients Review Expert Panel

In 1998, MPA asked the Cosmetics Ingredient Review (CIR) Expert Panel to review the use of MMA, MAA, EMA, and other methacrylate monomers in nail products, and to find such use inappropriate. CIR initially agreed to undertake a safety assessment of MMA, but after several years of review, it terminated its study, stating that it now supports FDA's position "against the use of MMA in nail enhancement products."⁸

MPA is aware that CIR has reviewed the use of other unreacted methacrylate monomers in nail products and considers their use safe when applied by trained technicians if all contact with the skin is avoided.⁹ CIR recognizes that these chemicals can cause contact dermatitis and sensitization. MPA disagrees with the CIR position and does not support the use of other unreacted methacrylate monomers in nail products because the risk of contact between the liquid monomer and the nail/skin cannot be avoided entirely.

⁷ See Product Safety Information for Nail Care Products, note 2 supra.

⁸ CIR, Final Report of the Safety Assessment of Methacrylate Ester Monomers Used in Nail Enhancement Products, 24 Int. J. Toxicology 53, 53 (2005).

⁹ CIR, Amended Final Report on the Safety Assessment of Ethyl Methacrylate, 21 Int. J. Toxicology 63 (2002); CIR, Final Report on the Safety Assessment of Methacrylic Acid, 24 Int. J. Toxicology 33 (2005); CIR, Final Report of the Safety Assessment of Methacrylate Ester Monomers Used in Nail Enhancement Products, 24 Int. J. Toxicology 53, 53 (2005).

The Hazards of Cosmetic Use

The hazards posed by use of unreacted MAA and methacrylate monomers in nail products have been recognized for many years and can be highlighted by several studies that were published around the time of and subsequent to MPA's petition to the CIR expert panel. Most significantly, Dr. Woolf's January 1998 article in the Archives of Pediatric and Adolescent Medicine collected reports of severe burns in children due to exposure to artificial nail primers whose primary ingredient was MAA. Dr. Woolf found the artificial fingernail primers were not polymers, but rather greater than 70% free MAA. As the article notes, some of these products may be intended for purchase by professional beauticians; but they are also widely available to, and used by, the consuming public given the current trend in artificial fingernail application toward more home application (of products intended for professional use). At home, caveats against skin contact are much less likely to be heeded, and accidental exposures of children have occurred.

The Woolf article supplements the extensive documentation of the corrosivity of the acid and the skin sensitization properties of the methacrylate monomers. Of most relevance to assessing whether acid or monomeric methacrylate use is appropriate in cosmetics are four recent studies. A skin irritation study of MAA in rabbits (Rohm and Haas 1997) found evidence of corrosivity with exposures as short as 3 minutes. Kanerva, et al. (1997) found 48 of 275 tested patients had allergic reactions to at least one methacrylate ester. Significantly, both MMA and EMA caused reactions in about 8% of the subjects. Rustemeyer et al. (1998) report on their recent research on the sensitizing properties of, and cross- reactivity patterns among, the methacrylates; they also include a summary of the extensive prior research on methacrylate sensitization. Tucker & Beck (1999) reviewed 14,000 patch tests administered over the past 15 years. MMA and EMA ranked similarly with 4.8% and 4.5%, respectively, positive results.

Other reports of adverse effects of MAA and MMA liquid acrylic monomers in nail products have been collected in the ECETOC Joint Assessment of Commodity Chemicals reviews of the acid and of MMA. All the reports indicate that each of the esters poses a sensitization and cross-sensitization risk that makes these industrial chemicals inappropriate for cosmetic use. A technical summary on the skin sensitizing properties of MAA and its short chain esters is available at <u>link</u>.

Conclusion

Through their product stewardship programs, MPA members have for many years recommended that MAA and its esters in their unreacted monomeric liquid form not be used in artificial nail products. Our position is supported by the information provided by FDA on its website. The MPA will continue to share with public health and governmental authorities the scientific literature concerning the corrosivity of MAA and the sensitization properties of its esters that make these compounds inappropriate for artificial nail product use.

State	Statutory or Regulatory Language	Statute or Regulation
Alabama	"No [cosmetology, manicure or esthetics] licensee shall use methyl methacrylate or any other product considered poisonous or unsafe."	Alabama Administrative Code 250-X-3.02(5)
Arizona	"An establishment shall not have on the premises cosmetic products containing hazardous substances banned by the U.S. Food and Drug Administration (FDA) for use in cosmetic products, including liquid methyl methacrylate monomer"	Arizona Administrative Code § R4-10-112(M)(1)
Arkansas	"The use [by licensed cosmetologists] of Liquid Methyl Methacrylate (MMA) Monomer is prohibited."	Arkansas Administrative Code § 007.30.1-12(K)
California	"No [barbering or cosmetology] establishment or school shall have on the premises cosmetic products containing hazardous substances which have been banned by the U. S. Food and Drug Administration for use in cosmetic products, including liquid methyl methacrylate monomer"	California Code of Regulations, Title 16, § 989
Colorado	"Licensed cosmetologists and manicurists may not use Methyl Methacrylate Liquid Monomers, a.k.a., MMA "	Colorado Code of Regulations § 731-1:9(B)(1)
District of Columbia	"A person may not use or possess methyl methacrylate liquid monomer (MMA) in a salon of any type in the District of Columbia."	District of Columbia Municipal Regulations, Title 17, § 3718.18(c)(1)
Delaware	"The use of methyl methacrylate (MMA) is prohibited. No [cosmetology or barbering] licensee, school or shop shall use or permit the use of MMA." "The use of methyl methacrylate (MMA) is prohibited [by cosmetologists and barbers]."	24-5100 Delaware Administrative Code § 14.3 16-4453 Delaware Administrative Code § 5.35
Florida	It is unlawful to, "[i]n the practice of cosmetology, use or possess a cosmetic product containing a liquid nail monomer containing any trace of methyl methacrylate (MMA)"	Florida Statutes § 477.0265(1)(h)

State Provisions Banning the Professional Cosmetic Use of Methyl Methacrylate (MMA)*

* This document is current as of April 2012 and includes only those state laws enacted and promulgated by that date.

Illinois	"The use of nail products or the distribution of nail products [by barbering, cosmetology, or esthetic licensees] containing monomer Methyl Methacrylate (MMA) is prohibited."	Illinois Administrative Code, Title 68, § 1175.115(b)(16)
Iowa	"No [cosmetology] salon or school shall have on the premises cosmetic products containing substances which have been banned or otherwise deemed hazardous or deleterious by the FDA for use in cosmetic products," including "any product containing liquid methyl methacrylate monomer"	Iowa Administrative Code r. 645-63.18(1)
Kentucky	"No instructor, student, cosmetologist, apprentice, or nail technician shall [u]se on any patron a liquid nail enhancement product containing monomeric methyl methacrylate for the purpose of creating artificial nail enhancements in the practice of cosmetology and nail technology."	Kentucky Revised Statutes § 317A.130(6)
Louisiana	"No beauty shop, salon or cosmetology school shall permit the use of and no individual licensed by the board shall use nail enhancement products containing methyl methacrylate (MMA) monomer."	Louisiana Administrative Code Title 46, § 701(R)(3)
Maryland	"A person may not use or possess methyl methacrylate liquid monomer (MMA) in a beauty salon in this State." "A person may not sell methyl methacrylate liquid monomer to a beauty salon"	Code of Maryland, Business Occupations and Professions, § 5-608.1(a) Code of Maryland, Health-General, § 24-303(a)
Michigan	"A [cosmetology] student, apprentice, or licensee shall not [u]se or possess methyl methacrylate monomers."	Michigan Administrative Code r. 338.2179g (1)(a)
Mississippi	"No product containing the ingredient methyl methacrylate (MMA) can be used in any manicuring or pedicuring procedure [performed by a cosmetology practitioner]. "	30-10 Code of Mississippi Rules 1:814(III)
Missouri	"No cosmetology licensee shall provide any cosmetology services that involve the use of any liquid product containing methyl methacrylate (MMA)."	Missouri Code of State Regulations Title 20, § 2085-11.020(2)(J)

Montana	"Use of methyl methacrylate monomers for artificial nails [by cosmetologists] is prohibited."	Administrative Rules of Montana 24.121.1517(3)(d)
New Hampshire	"A [cosmetology or esthetics] licensee shall not [a]pply methyl methacrylate (MMA) monomer on a person."	New Hampshire Code of Administrative Rules Bar. 302.07(g)(1)
New Jersey	"No licensee, licensed premise or school of cosmetology and hairstyling shall utilize any product that contains methyl methacrylate monomer."	New Jersey Administrative Code § 13:28-3.4(a)
New Mexico	"[T]he use, storage or dispensing of beauty service products containing methyl methacrylate or other chemicals determined to be hazardous to the health of licensees or consumers by the board of any federal, state or local health agency, shall be prohibited"	Code of New Mexico Rules § 16.34.7.9(A)(27)
New York	"No owner or operator of an appearance enhancement business shall knowingly sell, use or apply to any person monomeric methyl methacrylate; or direct any agent or employee of such business to sell, use or apply to any person monomeric methyl methacrylate."	New York General Business Law § 404-a(1)(a)
North Carolina	Cosmetic art licensees "must not use or possess in a shop Methyl Methacrylate Liquid Monomer a.k.a. MMA "	21 North Carolina Administrative Code 14H.0121(a)(1)
Ohio	No person shall "[u]se or possess a liquid nail monomer containing any trace of methyl methacrylate (MMA) [at a salon or school of cosmetology]."	Ohio Administrative Code 4713.14(N)(3)
Oklahoma	"The use of methyl methacrylate (MMA) is prohibited [in cosmetology establishments, salons, and schools]."	Oklahoma Administrative Code § 175:10-7-14(f)
Rhode Island	"The possession and/or use of any cosmetic nail preparation containing methyl methacrylate (MMA) shall be prohibited [for any cosmetician, manicurist, esthetician, or instructor]."	31-5 Rhode Island Administrative Code § 7:17.1.17
South Dakota	"A [cosmetology, esthetician, or nail technician] salon may not use [1]iquid monomer nail products containing methyl methacrylate monomers (MMA) "	Administrative Rules of South Dakota 20:42:04:08.01(1)

Tennessee	"Within a cosmetology, manicure or skin care shop, liquid methyl methacrylate products and other chemical substances and gases banned by the United States food and drug administration may not be used in any manner that is inconsistent with the requirements, terms and conditions of the ban." "No [cosmetology or barber] establishment or school shall have on the premises cosmetic products containing hazardous substances which have been banned by the United States Food and Drug Administration (FDA) for use in cosmetic products, including, but not limited to, liquid methyl methacrylate."	Tennessee Code § 62-4-133(b) Tennessee Rules and Regulations 0200-0306; 0440-0217.(1)
Texas	"[Cosmetology] [1]icensees may not use Methyl Methacrylate Liquid Monomers, a.k.a., MMA in performing cosmetology services"	16 Texas Administrative Code § 83.112(a)(1); 83.113(c)
Utah	"Unlawful conduct includes using or possessing as a nail technician a solution composed of at least 10% methyl methacrylate on a client."	Utah Administrative Code r. 58-11a-502(4)
Washington	"No [cosmetology, barber, manicurist, or esthetician] establishment or school may have on the premises cosmetic products containing hazardous substances which have been banned by the U.S. Food and Drug Administration for use in cosmetic products. Use of 100% liquid methyl methacrylate monomer [is] prohibited."	Washington Administrative Code § 308-20-110(16)
Wisconsin	"[Barbering and cosmetology] [1]icensees may not use methyl methacrylate monomer, commonly referred to as MMA in liquid form, and may not use any cosmetic or nail product formulated with MMA as one of its ingredients."	Wisconsin Administrative Code BC § 2.03(9)