

Via Electronic Submission: CalSafer

Meredith Williams, Ph. D Deputy Director, Safer Products & Workplace Program Department of Toxic Substances Control 1001 I Street Sacramento, CA 95814 gcregs@dtsc.ca.gov

April 8, 2020

Re: Safer Consumer Products Program: Product-Chemical Profile for Nail Products Containing Methyl Methacrylate (MMA)

Dear Dr. Williams:

COTY is pleased to submit the following comments on the Product-Chemical Profile for nail products containing Methyl Methacrylate (MMA) under California's Safer Consumer Products program, which was developed by the Department of Toxic Substances Control (DTSC) and made publicly available on January 30, 2020.

Coty, Inc. is a large, multi-national beauty company, founded in 1904. Among Coty's subsidiaries is OPI Products, Inc., a leading global manufacturer of salon nail care products. OPI was founded almost forty years ago in Los Angeles, where it remains,

We at COTY are strongly committed to the highest priority of the health and safety of our consumers through the marketing of cosmetics that are safe and effective, both from a human health and environmental perspective. Our products comply with all relevant and applicable laws and regulations.

Methyl Methacrylate monomer (MMA), a colourless, liquid organic compound, is the methyl ester of methacrylic acid. MMA is a large volume, bulk commodity chemical, 75% of which is used to make polymethyl methacrylate acrylic plastics (PMMA).¹ MMA is also a raw material for the manufacture of other methacrylates. These derivatives include ethyl methacrylate (EMA), the liquid monomer of choice used by the nail industry in artificial nail systems, butyl methacrylate (BMA) and 2-ethyl hexyl methacrylate (2-EHMA). Inevitably, there is some MMA residual in many of these derivatives. The projected annual volume of MMA sales

¹ https://en.wikipedia.org/wiki/Methyl_methacrylate

globally (2022) is over \$11 billion (USD).² The volumes attributable to the nail industry directly or indirectly are infinitesimally small.

MMA is sold by major chemical companies globally and is broadly used as a building block to make a range of polymer-based products from acrylic glass, car paints, toners, inks, and oil additives, to dental and medical products among others. Such broad and varied use makes MMA liquid monomer widely available to nail salon manufacturers and operators, who are not conforming to industry standards, at a significantly lower cost than the traditional, and more expensive derivative, EMA liquid monomer sold and used by responsible nail manufacturers and salons.

To create an acrylic nail on a client in a salon, the nail technician uses a two-part (liquid and powder) system, comprised of a liquid monomer (traditionally EMA) and a solid polymer nail powder (containing PMMA). The nail technician dips the tip of a long, artist brush into the liquid monomer and then dips that wet brush tip into the powder, picking up a small bead of the powder, spreading it onto the natural nail, which often has a form/template beyond the edge of the natural nail to lengthen and shape the resulting acrylic nail. When the wet brush tip hits the powder, polymerization begins and is quickly completed into a solid polymer or acrylic nail. The licensed nail technician is taught in cosmetology school and in follow-on continuing education, and so instructed on the label, and in accompanying materials, to avoid contact with the skin in the process.

The US FDA first became aware of complaints about 100% MMA monomers used in sculpturing acrylic nails in salons in the 1970's, taking judicial action to remove such monomers from the market, however the agency did not develop a regulation to ban MMA monomers.³ This judicial action and USF DA publicity concerning such action, as well as nail industry admonishments against its use, significantly reduced the usage of 100% MMA liquid monomers in artificial nails. Some time thereafter, MMA liquid monomer use began to increase again. In 2015, the nail industry, led by OPI Products, Inc., successfully worked together with the California Board of Barbering and Cosmetology to adopt formal regulations banning the use of MMA monomers in California nail salons, due primarily to technical issues with the ingredient itself, rather than any toxicological concerns.⁴

Methyl Methacrylate adheres poorly to the natural nail. In order obtain the appropriate level of adhesion of Methyl Methacrylate to the nail, nail technicians often rough up or "shred" the natural nail with a coarse file. This weakens and thins the natural nail, resulting in irritation and an increasing the risk of breakage. MMA creates a very hard nail enhancement, which can create a very painful removal process, which may lead to severe damage to the nail

² <u>https://www.marketsandmarkets.com/Market-Reports/methacrylate-monomer-market-99100473.html</u>

³ https://www.fda.gov/cosmetics/cosmetic-products/nail-care-products

⁴ California Code of Regulations, Title 16, Section 989, BBC 2015.

https://www.barbercosmo.ca.gov/laws_regs/art12.shtml#a989

itself. Due to these technical concerns, we believe, no responsible manufacturer, including OPI, currently sells MMA monomers or any nail care products containing purposely added Methyl Methacrylate.

MMA monomer has never been used in liquid monomers for sculptured nails, other than by manufacturers and salons not conforming to industry standards. MMA is present in other nail products only as a trace manufacturing residual in derived monomers (such as EMA liquid monomer) and in polymers (such as nail powders, glitters, and thickening agents in nail glues). Any residual amounts of MMA in polymerized MMA (PMMA), are locked into the polymer. The MMA cannot escape, except under the most extreme conditions. Much like a solid, polymerized, acrylic plaque, dish, or cup is not going to release MMA, so too a solid, polymerized, acrylic nail will not release MMA. Once polymerized, MMA does not "depolymerize" on removal. De-polymerize of PMMA would require extraordinarily high heat, in excess of 300 C, conditions not found in a nail salon.

With respect to residual levels of Methyl Methacrylate present in nail care products, concentrations of MMA can range up to 0.45% in EMA liquid monomers, in polymerized MMA (PMMA), and nail adhesives (glues). These levels pose no safety concern, resulting in a high Margin of Safety (MOS). Please see the below toxicological review. Moreover, it is also important to note that all licensed nail professionals are taught to avoid skin contact with artificial nail products and all artificial nail products contain instructions and warnings to such effect.

Product Type	Impurity Concentration (%)	Calculated Relative Daily Exposure (mg/kg/day)	Dermal Absorption (%)	% Residue (not polymerized)	Systemic Exposure Dosage (mg/kg/day)	NOAEL (mg/kg/day)	MOS
Nail Adhesive ª	0.45	66.67 ^b	100	1	0.00300	50	16667

° Nail adhesive - Assume worst-case 1.5% residual methyl methacrylate in formula containing 30% polymethyl methacrylate (thus 0.45% maximum methyl methacrylate)⁵

^b As there are no published exposure data for nail adhesive, utilized Scientific Committee on Consumer Safety (SCCS) assumptions from "Opinion on Trimethylbenzoyl Diphenylphosphine (TPO)" ⁶) for a nail modelling product; = 4 grams nail product applied / 60 kg body weight = 66.67 mg/kg; assumes 1% residue does not polymerize and is available for systemic exposure; SCCS does not consider frequency of application.

The regulations recognize that a Chemical of Concern may appear unintentionally in a product in a small or trace amount as a possible by-product of the manufacturing process,

⁵ California Department of Toxic Substances, "Product-Chemical Profile for Nail Products Containing Methyl Methacrylate (MMA) Discussion Draft – February 2020"

⁶ Scientific Committee on Consumer Safety, SCCs, "Opinion on Trimethylbenzoyl Diphenylphosphine (TPO)", March 27, 2014.

http://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_149.pdf

where the chemical does not directly contribute to the function or performance of the product; it is only found in the product as a contaminant associated with other chemicals that perform a function in the product. In these instances, the regulations provide an exemption from the requirements to conduct an AA when the Chemical of Concern does not exceed the applicable AA Threshold, which is the Practical Quantitation Limit (PQL) for that chemical. The regulations also note that DTSC may opt to specify in the final Priority Product-Chemical of Concern listing an AA Threshold greater than the applicable PQL for any Chemical of Concern that is a contaminant.

The detection of MMA in salon air, despite the California ban of MMA monomer and the small levels of trace residuals in other polymer products, nevertheless calls for an explanation. We respectfully submit, based on our experience in the industry, that MMA vapor in salon air is usually the result of illicit use of currently illegal MMA liquid monomer.

Given the low toxicological concern with current residual levels of MMA present in marketed products, we do not believe that Methyl Methacrylate meets the requirements to list it as a Priority Product. This is reinforced by the fact that MMA monomer in nail salons is already unlawful in the state of California.

Yours,

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