

Frequently Asked Questions (FAQs) for Professional Keratin Hair Smoothing Products

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Professional Keratin Hair Smoothing Products Frequently Asked Questions

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BACKGROUND

The use of so-called “keratin” hair smoothing products has become increasingly popular over the last several years. The wide use of these professional-use products has sparked varying concerns regarding the ingredients contained in these products and questions around potential safety issues.

In 2007, the Professional Beauty Association (PBA) issued the industry’s first advisory on the keratin hair smoothing category – encouraging salon professionals to educate themselves on these products. Specifically, PBA encouraged professionals to ask pertinent questions regarding product ingredients, appropriate handling, proper application techniques and any safety or allergy warnings that should be shared with consumers and stylists.

Additionally, the PBA called on manufacturers and distributors to provide industry professionals with all requisite information, training, and education necessary for the proper handling and safe application of hair smoothing products.

PURPOSE

As the nation’s largest organization of beauty industry professionals, the Professional Beauty Association is committed to providing relevant information to our members and the industry at large. The purpose of these FAQs is to provide interested persons with helpful information. This document is not intended to be a substitute for comprehensive training requirements, or to prescribe rules or standards, or to define or create legal rights or obligations.

Controversy around keratin hair smoothing products continues. The controversy relates to whether hair smoothing products release harmful amounts of formaldehyde or pose a threat to the health of customers or stylists. The studies continue, and the FDA, OSHA, and state agencies are reviewing potential health issues. One manufacturer brought a lawsuit against the Oregon OSHA alleging that the state agency had published slanted and scientifically incorrect information that had scared consumers and stylists. Reputable manufacturers have been very vocal in stating that these products are safe when used according to directions.

PBA will keep the industry apprised of developments in this area. We reiterate the need for manufacturers and distributors of these products to provide stylists and other industry professionals with up-to-date information, training, and education about how to safely apply and handle keratin products.

These FAQs will highlight some of the most-discussed issues.

Can formaldehyde be released during the application of professional-use-only keratin hair smoothing systems?

Yes. In some formulations of these hair smoothing systems, formaldehyde is present in water or water-containing formulations and exists mostly as methylene glycol with almost no gaseous formaldehyde remaining. However, when heated and dried during the application process, it is possible that some formaldehyde can be released into the air and may be inhaled by salon professionals and consumers.

The application of some smoothing products, including keratin smoothing systems, involves heating the product on the hair using a flat iron or similar heated device. Temperatures used typically

exceed 300°F (149°C). Heating products containing methylene glycol to these temperatures can cause the release of formaldehyde gas. Previous uses of methylene glycol have not generally required heating, so this is a somewhat new application that has not been studied comprehensively.

What is formaldehyde?

Formaldehyde is a dry, colorless gas with a distinctive, pungent odor. It can be irritating to the eyes, nose, and throat.¹ An expert panel review of over 150 published studies found that eye irritation becomes significant at around 1.0 ppm (parts per million- in air), and moderate to severe eye, nose, and throat irritation occurs at 2.0-3.0 ppm.²

Formaldehyde's primary risk to humans is from direct inhalation of the gas at relatively high concentrations and for long periods of time. Overexposure to formaldehyde gas via inhalation can produce adverse effects and irritation of the eyes, nose, and throat and nasal cavity, as well as coughing, wheezing, chest pains, and bronchitis. The general public is exposed to low amounts of formaldehyde gas through many sources and there are safe levels of exposures, as well as risky levels.

Formaldehyde is a naturally occurring organic compound that is created and released by plants and animals. It is also a normal by-product of human metabolism.

In household settings, the U.S. Environmental Protection Agency (EPA) reported that a survey of homes found formaldehyde levels of 0.10-3.68 ppm. Higher levels have been reported in manufacturing facilities and mobile homes. In ambient outdoor air, the EPA reports there is between 11.0-30.0 ppb (parts per billion) at any given time.³

What potential areas of concern exist with formaldehyde?

Commonly present in preservatives, formaldehyde can be released from everyday household objects such as glue and particle board. However, acute exposure can be highly irritating and may cause severe allergic reactions of the skin, eyes and respiratory tract. Individual reactions to different levels of formaldehyde (as with most environmental stimuli) can vary greatly based on hereditary and lifestyle factors.

The majority of formaldehyde exposure occurs by inhalation or through skin contact. The U.S. Environmental Protection Agency (EPA) and federal Occupational Safety and Health Administration (OSHA) regard formaldehyde as a possible human carcinogen and regulate it accordingly.

In 2009, the International Agency for Research on Cancer (IARC) classified formaldehyde as a "known human carcinogen".⁴ This is a potential risk for workers in settings where high levels of exposure are possible. IARC's classification appears to have been based on findings for formaldehyde at high concentrations with exposure to gaseous formaldehyde such as those seen in industrial settings.

What government agencies are responsible for regulating salon safety?

Workplace safety, including air quality, is regulated by the Occupational Safety and Health Administration (OSHA). Additionally, salons are generally subject to state and local authorities, which may have their own specific safety practices such as ensuring proper ventilation.

¹ Dennis Paustenbach, et al, "A Recommended Occupational Exposure Limit for Formaldehyde Based on Irritation," Journal of Toxicology and Environmental Health, Part A Feb. 1997: 217-64.

² Joel Bender, "The Use of Noncancer Endpoints as a Basis for Establishing a Reference Concentration for Formaldehyde," Regulatory Toxicology and Pharmacology, Feb. 2002: 23-31

³ United States Environmental Protection Agency, Formaldehyde, 6 Nov. 2007, 23 Nov. 2010
<http://www.epa.gov/ttnatw01/hlthef/formalde.html#ref1>

⁴ World Health Organization, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, 23 Nov. 2010
<http://www.inchem.org/documents/iarc/vol88/volume88.pdf>.

Although the U.S. Food and Drug Administration (FDA) does not have authority over the operations of salons and spas, it does have certain authority over hair straighteners and similar cosmetic products.

What kind of authority does the FDA have over personal care products?

The FDA regulates cosmetics under the authority of the Federal Food, Drug, and Cosmetic Act (FD&C Act, or the Act). Under the Act, cosmetics must be safe for consumers under labeled or customary conditions of use, and they must be properly labeled. However, the FDA has no authority under the FD&C Act to “issue” a recall of a cosmetic, although they can request that a firm voluntarily recall a product if they have solid evidence of a violation of the law.

The FDA can also take other regulatory action against products marketed in violation of the law and against the companies and individuals who market them.

In October 2010, the FDA posted an advisory stating that it had received complaints against a specific keratin hair smoothing brand. The FDA notice can be found online at <http://www.fda.gov/Cosmetics>. FDA noted that it was working with state and local groups, as well as OSHA, to determine whether the keratin products or ingredients are likely to cause health problems under their intended conditions of use. The agency stated that the product composition and labeling, including warnings and instructions, are key factors in this determination.

Is exposure to formaldehyde permissible in the workplace?

Yes. OSHA has defined what formaldehyde limits are acceptable in the workplace. The OSHA standard that protects workers exposed to formaldehyde apply to all occupational exposures to formaldehyde, including formaldehyde gas and materials that release formaldehyde.

The permissible exposure limits (PELs) for formaldehyde in the workplace covered by the standard are 0.75 parts formaldehyde per million parts of air (0.75 ppm) measured as an 8-hour time-weighted average (TWA).⁵

The standard includes a second permissible exposure limit (PEL) in the form of a short-term exposure limit of 2.0 ppm that is the maximum exposure allowed during a 15-minute period.

The action level- which is the threshold for increased industrial hygiene monitoring and initiation of employee medical surveillance – is 0.5 ppm when calculated as an 8-hour TWA.

What levels of formaldehyde are considered normal?

According to the U.S. Environmental Protection Agency (EPA), formaldehyde is normally present at low levels, usually less than 0.03 ppm, in both outdoor and indoor air.⁶ The outdoor air in rural areas has lower concentrations while urban areas have higher concentrations. Homes and businesses that contain products that release formaldehyde to the air may have formaldehyde levels of greater than 0.03 ppm. Products that may add formaldehyde to the air include particleboard used as flooring underlayment, shelving, furniture and cabinets; Medium-density fiberboard (MDF) in cabinets and furniture; hardwood plywood wall panels, and urea-formaldehyde foam used as insulation. As formaldehyde levels increase, illness or discomfort is more likely to occur and may be more serious.

Isn't formaldehyde in beauty products limited to 0.2 percent?

In 2005, the Cosmetic Ingredient Review (CIR) Expert Panel, an independent, non-profit body of scientific and medical experts that evaluates the safety of ingredients used in cosmetics in the United

⁵ Occupational Safety and Health Administration, OSHA Fact Sheet, 2002, 23 Nov. 2010 http://www.osha.gov/OshDoc/data_General_Facts/formaldehyde-factsheet.pdf.

⁶ United States Environmental Protection Agency, Formaldehyde, 6 Nov. 2007, 23 Nov. 2010 <http://www.epa.gov/ttnatw01/hlthef/formalde.html#ref1>.

States, evaluated the use of formaldehyde-releasers in beauty products. The CIR's conclusion at that time was that "...because of skin sensitivity of some individuals to this agent, the formulation and manufacture of a cosmetic product should be such as to ensure use at the minimal effective concentration of formaldehyde, not to exceed 0.2 percent measured as free formaldehyde".⁷

The main consideration by the CIR during this review was the use of formaldehyde-releasing preservatives to prevent the growth of potentially harmful microorganisms in beauty products. It is important to note that the Cosmetic Ingredient Review (CIR) **did not evaluate hair straightening treatments and the presence of formaldehyde.**

However, the CIR is expected to evaluate ingredient issues surrounding hair smoothing products in the near future. In January 2011, the Professional Beauty Association officially requested that the Cosmetic Ingredient Review examine the presence of methylene glycol and release of formaldehyde during the application of professional hair straightening treatments.

Do professional smoothing products release levels of formaldehyde that are above OSHA's permissible limits?

We have found no comprehensive and objective studies that have been conducted on this category of products. In October, 2010, the Oregon OSHA released a report titled "Keratin-Based Hair Smoothing Products And the Presence of Formaldehyde." That report concluded that excessive amounts of formaldehyde were present in the brand(s) of keratin product tested.⁸ However, this report has been challenged by a manufacturer as not reliable or scientifically valid. To our knowledge, this is the only study on keratin smoothing products issued by a state or federal regulatory agency.

As part of their research, Oregon OSHA conducted air monitoring during keratin smoothing treatments – testing a single product brand – in seven different salons where a single treatment was conducted over the course of one day. Oregon OSHA tests concluded that all air monitoring test results done on the keratin process came in under OSHA's permissible limits for formaldehyde.

What did Oregon OSHA find out about formaldehyde levels in the salons they tested?

Air samples were taken in seven salons as part of Oregon OSHA's testing. The exposures varied widely depending on many factors – including ventilation, room size, and duration of the treatments. Oregon OSHA reported that in each of the seven salons tested, none of the exposure levels exceeded the permissible exposure limits (PELs) allowed under federal OSHA regulations.

Oregon OSHA pointed out in their report that in certain scenarios, there could be a point where enough treatments are performed in the salon in a given time period so as to cause the release of formaldehyde in quantities that could exceed OSHA's PELs. The Oregon OSHA report concluded that salon workers confront certain risks when handling and applying these keratin hair smoothing products. It further noted that controlling those risks depends on accurate information regarding the product ingredients and their potential hazards, and measures to address and control those risks.

Although Oregon OSHA's tests did not show that formaldehyde exceeded permissible limits in the salon tests, Oregon OSHA noted that other organizations have lower recommended exposure limits. For example, the National Institute for Occupational Safety and Health (NIOSH) has a recommended exposure level (REL) of 0.016 ppm as an 8-hour time weighted average, as well as a 15-minute short term exposure limit of 0.1 ppm. NIOSH-recommended limits were exceeded in all the air monitoring conducted by Oregon OSHA. It is important to note however that NIOSH recommendations do not carry the force of law as OSHA limits do.

⁷ Cosmetic Ingredient Review, Quick Reference Table, June 2010, 23 Nov. 2010 http://www.cir-safety.org/staff_files/PublicationsListDec2009.pdf.

⁸ United States, Oregon Occupational Safety and Health Administration, "Keratin-Based" Hair Smoothing Products And the Presence of Formaldehyde, Kermit McCarthy, David McLaughlin, Dede Montgomery, Peggy Munsell, Marilyn Schuster, and Michael Wood, 29 Oct. 2010 http://www.orosha.org/pdf/Final_Hair_Smoothing_Report.pdf.

Have there been other official actions relating to these products?

Not in the U.S. However, in December 2010, Health Canada issued an advisory warning Canadians about certain professional hair smoothing solutions that contained levels of formaldehyde above the limit set by Health Canada. It is not known whether the manufacturers challenged that warning or the validity of the scientific testing.⁹

Where can I find more information about safe handling of professional-use-only salon products?

Read and follow manufacturers' instructions for products used in the salon. Labels include information about how to use products safely, expiration dates, and safety precautions to be followed in case of a spill or reaction, and proper disposal. Also, be sure to follow local, state, and federal regulations for chemical disposal.

Have a Material Safety Data Sheet (MSDS) on file in your salon for every product used in the salon that could cause injury or harm. MSDS include important information about reactions, spills, ingredients, and disposal of chemicals. Make certain that the information on the MSDS is read and understood by all salon workers. If you do not have an MSDS for certain products, ask the distributor or manufacturer for a copy, or why no MSDS is available (if that is the case).

Most states require MSDS to be available upon request by an inspector, and salons may be subject to fines if they don't have them. So salons should keep MSDS for all products in an easily accessible location. Many manufacturers have MSDS on their websites that can be easily downloaded.

Included in these FAQs is a Helpful Resources page that lists useful websites. You can also visit www.probeauty.org/keratin for a listing of these helpful websites and a downloadable copy of these FAQs.

What is likely to happen next regarding keratin hair smoothing systems?

PBA urges its members to be alert for any developments and to ensure that products are handled appropriately and in well-ventilated areas. We will continue to monitor the situation and to report on developments.

How can I report an adverse experience related to a cosmetic or beauty product?

- 1) Report adverse reactions to product manufacturers and distributors.
- 2) Report to the nearest FDA district office. Phone numbers for their complaint coordinators are posted on FDA's Web page at <http://www.fda.gov/Safety> and in the Blue Pages of the phone book, generally under United States Government/Health and Human Services.
- 3) Reporting online to FDA's at <http://www.fda.gov/Safety>. You also may call Medwatch at 1-800-332-1088 to request a reporting form by mail.
- 4) PBA, as part of its commitment to safety in the professional salon industry, always welcomes comments about safety. Send an email to: info@probeauty.org

⁹ Health Canada, Advisory, 10 Dec. 2010 http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2010/2010_222-eng.php

HELPFUL RESOURCES

Professional Beauty Association

<http://probeauty.org>

CosmeticsINFO.org

<http://www.cosmeticsinfo.org>

Cosmetic Ingredient Review (CIR)

<http://www.cir-safety.org>

U.S. Food and Drug Administration (FDA)

<http://www.fda.gov>

Occupational Safety and Health Administration (OSHA)

<http://www.osha.gov>

Center for Research on Occupational and Environmental Toxicology (CROET)

Oregon Health & Science University

<http://www.ohsu.edu/xd/research/centers-institutes/croet>

Chemical Abstracts Service

<http://www.cas.org>

Personal Care Products Council (PCPC)

<http://www.personalcarecouncil.org>

The National Institute for Occupational Safety and Health (NIOSH)

<http://www.cdc.gov/niosh>

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