Professional “Keratin” Hair Smoothing Products

Frequently Asked Questions

March 2011; updated November 2011

**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. Most controversy has surrounded the issues of whether the products contain or emit formaldehyde, what precautions should be taken by salon professionals, and whether these products should be subject to additional safety and use regulations. In recent months, OSHA, the FDA, the Cosmetic Ingredient Review panel, and state agencies have issued “hazard alerts” and advised or taken other regulatory actions.

In view of these actions, we expect additional regulatory and legal action, as well as additional product information from the manufacturers and importers of the “keratin” hair smoothing products. PBA will continue to keep salon professionals and other industry members aware of these issues through these FAQs as well as the informational links, press releases, and other resources on PBA’s dedicated webpage, www.probeauty.org/keratin.

**History**

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 and ventilation, proper application techniques and any safety or allergy warnings that should be shared with consumers and stylists.

On December 9, 2010, PBA sent a letter to the CIR asking them to re-exam the use of formaldehyde releasers in cosmetics, and to initiate a formal examination of the use of methylene glycol in personal care and beauty products. The CIR is an independent, non-profit body of scientific and medical experts that assesses the safety of ingredients used in cosmetics in the U.S. As a result of the request by PBA, the Personal Care Products Council and the FDA, the CIR launched a review of keratin hair smoothing and other beauty care products with formaldehyde or related ingredients.

At first, at the CIR’s meeting in March 2011, the CIR concluded that there was insufficient data to determine if there should be changes to the allowed ingredient limits and uses that were previously determined for formaldehyde-related products and the CIR requested additional information for its study. In March 2011, PBA released the first version of these FAQs: Professional Keratin Hair Smoothing Products, to provide education and information regarding the use of hair smoothing products. As PBA had done in 2007, the FAQs urged industry members handling keratin hair straightening products to educate themselves about the ingredients review the manufacturer’s information and take steps to ensure safe handling and ventilation when using these products.
In October, 2011, after further review and a September 2011 meeting in Washington, DC, the CIR issued a final report concluding that formaldehyde and methylene glycol are unsafe in the present practices of use and concentration in hair smoothing products (aka hair straightening products). The CIR report follows an OSHA Hazard Alert (last updated in September, 2011) and legal actions against some product manufacturers, as well as an FDA Warning Letter (which has been contested by the product manufacturer). In view of these actions, we expect additional developments, and will keep PBA members apprised of them.

**Purpose of these FAQs**

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 the 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. 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. Stylists and salon owners also should review the MSDS and other product information and take appropriate handling and ventilation measures. Any health problems or adverse reactions should be reported to salon management, manufacturers, and government officials as appropriate (see links below).

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

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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.\textsuperscript{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.\textsuperscript{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”.\textsuperscript{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

\textsuperscript{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

\textsuperscript{3} United States Environmental Protection Agency, [Formaldehyde](http://www.epa.gov/ttnatw01/hlthef/formalde.html#ref1), 6 Nov. 2007, 23 Nov. 2010;

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.

OSHA has posted Hazard Alert Updates on their website. The most recent update is dated September 22, 2011 regarding hair smoothing products containing formaldehyde (see discussion below). The National Institute for Occupational Safety and Health (NIOSH) has also completed a Health Hazard Evaluation for salon workers that assessed risks posed from using a specific hair smoothing product in a single salon.

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 about some keratin hair-smoothing products. The FDA notice can be found online at [http://www.fda.gov/Cosmetics](http://www.fda.gov/Cosmetics) and [http://www.fda.gov/Cosmetics/ProductandIngredientSafety/ProductInformation/ucm228898.htm](http://www.fda.gov/Cosmetics/ProductandIngredientSafety/ProductInformation/ucm228898.htm).

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. The FDA has stated that formaldehyde released into the air can cause serious irritation of eyes, nose and lungs. The FDA has recommended that exposure to products with formaldehyde-related ingredients be limited, in order to reduce health risks.

On August 22, 2011, the FDA sent a warning letter to a manufacturer of keratin hair-straightening products. A copy of this letter is available on our PBA website, probeauty.org/keratin. According to the FDA warning letter, the FDA had concluded that the subject product was adulterated and misbranded under the federal Food, Drug, and Cosmetic Act. The FDA asserted that the professional hair-straightening product was considered adulterated due to the presence of methylene glycol and misbranded because it was labeled "formaldehyde free" and did not contain warnings or sufficient information concerning the possible release of formaldehyde-related ingredients. The company sent the FDA a response rebutting the points in the FDA's letter. The FDA has not released the company’s response, however, as the FDA considers it to be part of the agency’s investigative records.

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5The FDA letter to GIB, LLC is also available at [http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm270809.htm](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm270809.htm).
Is exposure to formaldehyde permissible in the workplace?

Yes, some exposure to formaldehyde is permissible in the workplace. 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). 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.

In addition, the National Institute for Occupational Safety and Health (NIOSH) has issued “Recommended Exposure Limits” or RELs for exposure to formaldehyde in the workplace. The NIOSH REL for formaldehyde is 0.016 ppm for up to a 10-hour TWA, with a 15-minute ceiling limit of 0.1 ppm that should not to be exceeded during a work shift. The NIOSH limits are recommended levels based on science; the OSHA limitations are legally enforceable standards.

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. 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 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

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minimal effective concentration of formaldehyde, not to exceed 0.2 percent measured as free formaldehyde”.9

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.

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.

The CIR met in September 2011 and concluded that formaldehyde and methylene glycol are safe for use as a preservative in cosmetics when formulated to ensure use at the minimal effective concentration and nail hardening products in the present practices of use and concentration; however, unsafe in the present practices of use and concentration in hair smoothing products (aka hair straightening products). The CIR’s conclusion was published in October 2011, in its Final Amended report on Formaldehyde and Methylene Glycol.

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

The manufacturers of professional hair smoothing products maintain that their products do not release formaldehyde over OSHA permissible limits during usage and application. These manufacturers have issued safety tips on proper use and application procedures and urge salon professionals to follow the manufacturer’s directions and review the product MSDS.

Some agencies have reported test results showing excessive levels of released formaldehyde. For example, 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.10 However, this report was challenged by a manufacturer as not reliable or scientifically valid.

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

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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 the NIOSH recommended limits were exceeded in all the air monitoring they conducted.

**Has OSHA taken any actions concerning keratin products?**

As mentioned, OSHA issued a “Hazard Alert” concerning hair-straightening products that could contain formaldehyde and result in possible formaldehyde exposure. The Alert notes that Federal and State OSHA have investigated complaints from stylists and hair salon owners about possible exposure to formaldehyde while using hair smoothing products. The Hazard Alert mentions the Oregon and other state investigations and sets forth OSHA requirements for the labeling, use and workplace precautions for products containing formaldehyde.

OSHA requires manufacturers of products that contain or release formaldehyde to include information about formaldehyde and its hazards on the label and in the MSDS. Formaldehyde must be listed if it is in the product at 0.1% or more (as a gas or in solution) or if the product releases formaldehyde above 0.1 parts of formaldehyde per million parts (ppm) of air.

Under OSHA’s Formaldehyde Standard, if a product contains 0.1% or more formaldehyde or can release formaldehyde into the air above 0.1 ppm, the product label must state that the product contains formaldehyde and that health hazard information can be obtained from the employer or the MSDS. Additionally, if the product can release formaldehyde into the air above 0.5 ppm, the label must also list all product health and safety hazards and be labeled "Potential Cancer Hazard." The product manufacturer must provide Material Safety Data Sheets with safety warnings, safe handling and usage instructions, and other pertinent information as required by OSHA’s regulations. In addition, employers must provide adequate training and information, as well as possible testing and record-keeping, as prescribed under the OSHA regulations.

The OSHA Hazard Alert states that: “If salon owners decide to use products that contain or release formaldehyde, then they must follow the requirements in OSHA’s Formaldehyde standard. The standard requires that employers test the air to find out the level of formaldehyde

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12 OSHA, 29 CFR 1910.1048(m).

present in the air when the product is being used. If the test shows that formaldehyde is present at levels **above OSHA's limits** (0.75 parts of formaldehyde per million parts (or ppm) of air during an 8-hour work shift or 2 ppm during any 15-minute period), then the employer must:

- Install air ventilation systems in the areas where these products are mixed and used to help keep formaldehyde levels below OSHA's limit and perform regular maintenance to make sure the systems work correctly;
- When possible, require workers to use lower heat settings on blow-dryers and flat irons used during the process;
- Give workers respirators, if needed; train them to use the respirator properly; and meet the other requirements in OSHA's Respiratory protection standard, **29 CFR 1910.134**;
- Ensure workers understand the information on a product's label and MSDS;
- Post signs at entryways to any area where formaldehyde is above OSHA's limit to tell workers of the danger and stating that only authorized personnel may enter;
- Tell workers about the health effects of formaldehyde, how to use the product safely, and what personal protective equipment to wear while using the product; and
- Train workers how to safely clean up spills and properly throw products out.”

The Hazard Alert also advises that, whether or not air tests show formaldehyde levels above OSHA's limits, employers must follow certain parts of the OSHA Formaldehyde Standard if a product contains any formaldehyde:

- Employees must be given appropriate gloves and other personal protective equipment (e.g., face shields, goggles, chemical-resistant aprons);
- Employees must be trained on how to use the protective equipment while handling and applying the products;
- Employers must explain how to read and understand the information on a product's label and MSDS;
- Employers must ensure that the workplace has eye and skin washing equipment if the products with formaldehyde could be splashed onto the employees' skin or eyes;
- Employees must be trained how to safely clean up spills and dispose of products;
- Employees must be provided with medical attention (e.g., doctor exams) if they develop signs and symptoms of an exposure to formaldehyde or are exposed to large amounts of formaldehyde during an emergency (e.g., a large spill).14

The salons also must keep records of testing and any medical attention needed by employees as a result of the use of these products. Salon management also should make sure that their MSDS materials are up to date and available to employees. OHSA investigators have visited specific salons after receiving complaints, to test for formaldehyde in the air and to assess whether salons are in compliance with the OSHA regulations. It therefore is very important that the salon owners understand their requirements and implement safety and compliance programs that meet the federal and state OSHA standards.

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Have there been other official actions relating to these products?

As noted above, the FDA has issued a warning letter to a manufacturer, which is available on PBA’s webpage, probeauty.org/keratin. There may well be further FDA follow-up, now that the manufacturer has responded to the FDA’s letter. In addition to the Oregon OSHA investigation mentioned above, California, Connecticut and New York state agencies also have issued warnings about hair straightening products that may contain or result in formaldehyde emissions when used.

Additionally the CIR findings issued in September 2011 and contained in an November 2011 Final Report concluded that formaldehyde and methylene glycol are unsafe in the present practices of use and concentration in hair smoothing products (aka hair straightening products). We will monitor further developments to see if the CIR Final Report results in further actions.

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.\textsuperscript{15}

In September 2011, OSHA cited two Florida manufacturers and two Florida-based distributors of hair-straightening products for alleged non-compliance with OSHA regulations. The citations alleged that the companies had failed to protect their employees from possible formaldehyde exposure and had not sufficiently informed the salons and stylist users of the products about the potential hazards of formaldehyde exposure. OSHA proposed penalties of over $49,000 against the companies.\textsuperscript{16}

In addition, some salons and salon workers have filed lawsuits against manufacturers and/or importers of keratin hair-straightening products. The lawsuits have complained of false or misleading advertising and labeling, or have alleged injuries resulting from exposure to formaldehyde. In California, class actions have been filed challenging the labeling and composition of certain keratin products.\textsuperscript{17}

In November 2010, the California Attorney General also filed a lawsuit against a manufacturer of keratin hair-straightening products. The complaint asserted that the company did not give a required Proposition 65 warning about potential exposure to formaldehyde and failed to take other actions under California laws.\textsuperscript{18}


\textsuperscript{17} One class action lawsuit is In Re Brazilian Blowout Litigation, CV 10-8452-JFW (MANx)(C.D. Cal.). Discovery is underway in that case, which is hotly contested by the manufacturer.

\textsuperscript{18} The lawsuit is People of the State of California v. GIB, LLC, Case No. RG-10545880 (Cal. Sup. Ct. 2010).
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?

Due to recent CIR findings and the OSHA and other alerts, 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) File a complaint with OSHA, at http://www.osha.gov/as/opa/worker/complain.html, or contact an OSHA Regional Office. For more information, see http://www.osha.gov/html/RAmap.html.

5) 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
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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