

Decision Document for Hair Straightening Products Containing Formaldehyde

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1. ABOUT THIS DOCUMENT

The use of formaldehyde in hair straightening products has been a concern, and an intermittent subject of research, of the Department of Toxic Substances Control's (DTSC's) Safer Consumer Products (SCP) Program since its inception in 2013. In May 2021, we released a document summarizing some of our work – <u>Chemicals in Hair Straightening Products Background Document</u>.

This decision document outlines the key findings of our evaluation of hair straightening products that contain formaldehyde. Our overarching question: would regulating these products under the Safer Consumer Products Program's regulatory framework meaningfully enhance protection of hair salon workers and their customers who use the products frequently? We are providing this information to provide transparency about our decision-making process and to highlight the considerable effort that went into evaluating formaldehyde in hair straightening products.

2. BACKGROUND

Formaldehyde occurs naturally in most living systems, but its presence in the environment is largely a result of industrial emissions (IARC 2012). It is a colorless, strong-smelling gas that is often used in aqueous solutions (OSHA 2011a). In products, the presence of formaldehyde may be indicated by the listing of ingredient names such as methylene oxide, paraformaldehyde, formic aldehyde, methanal, oxomethane, oxymethylene, formalin, and methylene glycol (NIOSH 2011). The U.S. Environmental Protection Agency (U.S. EPA) reports that the national production volume for formaldehyde was between one and five billion pounds in 2019 (U.S. EPA 2024). It is estimated that more than 12 million tons of formaldehyde were used in the United States in 2020 (ReportLinker 2020). Formaldehyde is used in consumer products for various purposes, including as a preservative in cosmetics, detergents, disinfectants, and cleaning agents; as a binding agent in adhesives, paints, and lacquers; and as a hardener in nail care products (ECHA 2017; FDA 2020).

Formaldehyde is a human carcinogen and suspected mutagen (ECHA 2023). Formaldehyde exposure is also associated with an increased risk of asthma, allergies, and a range of other adverse health impacts (Mendell 2007 and Sakamoto et al. 1999 as reviewed by ATSDR 2010; ACGIH 2012). The National Occupational Exposure Survey, conducted in the 1980s, estimated that 1,329,332 workers were exposed to formaldehyde (ATSDR 1999). Sensitive populations at greatest risk of experiencing harmful effects from formaldehyde exposure include people with asthma, those with respiratory or dermal sensitization to the chemical, people with heightened chemical sensitivity, and workers (ATSDR 1999; ATSDR 2010).

3. PROBLEM STATEMENT

Certain hair straightening products contain formaldehyde or chemicals that produce formaldehyde when heated. These products can expose workers and hair salon customers to formaldehyde and harm their health. Salon workers have the greatest potential exposure because they may work with hair straightening products for prolonged periods daily (Pierce et al. 2011). These workers (hairdressers and allied professionals) represent a large and fast-growing occupational group, with more than 618,000 estimated jobs and a projected 8% growth in the workforce in the next ten years (U.S. BLS 2023a). As of May 2023, there were about 294,840 hairdressers in the U.S. and 20,450 hairdressers in California (U.S. BLS 2023b). The Occupational Safety and Health Administration (OSHA) evaluates worker exposure to formaldehyde in all its forms (OSHA 2013); several studies by others have shown that salon workers can be exposed to formaldehyde from hair straighteners at levels that exceed occupational limits (Oregon OSHA and CROET 2010; Pierce et al. 2011; Stewart et al. 2013).

Salon customers may also be exposed to formaldehyde, both during application of the hair straightener and in the drying and ironing process that follows; these exposures have the potential to result in adverse impacts (Pierce et al. 2011). While inhalation is the most concerning route of exposure to formaldehyde from these products, absorption through the skin can also occur (ATSDR 1999; ATSDR 2010).

Of notable concern, Black women [women of African descent¹] purchase and use hair straightening products that often contain formaldehyde at higher rates than women of other races and ethnicities (Zota and Shamasunder 2017). These initial findings provided a compelling basis for identifying formaldehyde in hair straighteners as a Priority Product.

4. KEY FINDINGS

We found several areas of concern around the presence of formaldehyde in hair straightening products, including high concentrations of the chemical in keratin-based products, high concentrations in indoor air in salons, and reports of adverse health impacts resulting from exposure to formaldehyde in hair straightening products.

¹For inclusivity and consistency in our document, we use the term African descent to identify individuals with places of ancestral origin in Sub-Saharan or North Africa. When citing research, we will use the terminology used within the study to ensure we are portraying the authors' findings accurately. For additional rationale on the use of this term, refer to Appendix A in our <u>Chemicals in Hair</u> <u>Straightening Products Background Document</u>.

Keratin-Based Products

Keratin-based hair straightening products can contain formaldehyde and its derivatives (formalin or methylene glycol) as the main ingredient. Formaldehyde can act as a fixative to cross-link the hair's natural keratin with the keratin introduced in the product, resulting in straightened hair or smoothed out curls (Boyer et al. 2013; Weathersby and McMichael 2013; Cruz et al. 2017). A serum containing hydrolyzed keratin and formaldehyde derivates is combed or brushed onto small sections of washed hair until all the hair is coated (Weathersby and McMichael 2013). The hair is then blow-dried and flat-ironed at 450 °F to seal the keratin onto the hair (CDC 2011; Weathersby and McMichael 2013). Formaldehyde gas is released into the air during the blow drying and flat ironing steps (Pierce et al. 2011; Weathersby and McMichael 2013). Many stylists further recommend that their clients wait 48 to 72 hours before washing their hair to allow the chemicals to set (Weathersby and McMichael 2013).

Pierce et al. (2011) found high concentrations of formaldehyde (3 to 11.5%) in bulk sampling of keratinbased hair straightening products, with the highest concentration found in a product labeled formaldehyde-free. Some hair straightening products have undergone reformulation and claim to only use methylene glycol; however, this chemical is formaldehyde in solution. The Cosmetic Ingredient Review (CIR) states that using formaldehyde or methylene glycol in hair straightening products is unsafe due to the concentrations present and how they are used (CIR 2022). Despite efforts to reformulate products, studies such as Pierce et al. (2011) show that improper labeling and continued use of formaldehyde in its different forms may lead to unintentional exposures among workers and consumers.

Hazard Traits

Formaldehyde is a human carcinogen and suspected mutagen (ECHA 2023). The International Agency for Research on Cancer (IARC) Working Group and the National Toxicology Program (NTP) both concluded that formaldehyde causes nasopharyngeal cancer, sinonasal cancer, and leukemia, based on epidemiological studies of industrial workers and professional groups such as pathologists, funeral directors, and embalmers (IARC 2012; NTP 2016; Committee on Review of EPA's 2022 Draft Formaldehyde Assessment et al. 2023).

Additionally, dermal sensitization to formaldehyde in humans is well recognized (ATSDR 1999; ATSDR 2010). The ACGIH recognizes formaldehyde as a sensitizer, based on reports of allergic reactions/sensitizations following occupational and non-occupational exposures (ACGIH 2012). Skin sensitization reactions include eczema, respiratory symptoms such as breathing discomfort and cough, and headache and nausea (ATSDR 2010). Not only can sensitizers like formaldehyde cause allergic reactions in some individuals, but they also increase the risk that exposed individuals will react to the substance in the future, perhaps at much lower exposures. Formaldehyde can also cause severe skin burns (ECHA 2023).

Formaldehyde affects the respiratory system as well. Because of its high reactivity and solubility in water, formaldehyde is able to enter the mucus layers of the eyes and respiratory system and cause irritation (OEHHA 2008). Nose and throat irritation is a symptom reported by workers exposed to formaldehyde via inhalation (ATSDR 2010). At high concentrations, the lungs are a secondary target of adverse health impacts (ATSDR 1999; ATSDR 2010).

Inhalation of formaldehyde may produce or exacerbate allergic effects of asthma in children or adults (Mendell 2007 and Sakamoto et al. 1999 as reviewed by ATSDR 2010). Formaldehyde exposure is linked to bronchoconstriction (a symptom of asthma), coughing, wheezing, and bronchitis (U.S. EPA 2000; OEHHA 2008). The effects of formaldehyde on people with asthma may depend on previous, repeated exposure to formaldehyde. One study found that three out of 15 workers exposed to formaldehyde vapors at work (1.5 to 20.6 parts per million (ppm) for brief durations) showed delayed asthmatic reactions rather than immediate effects (Burge et al. 1985).

Eye irritation is another well-documented symptom of formaldehyde inhalation exposure. This occurs at similar exposure concentrations to those that induce irritation of the upper respiratory tract (ATSDR 1999; ATSDR 2010). Additionally, formalin (a liquid solution of formaldehyde (CAMEO Chemicals 2023)) splashed in the eyes can result in damage to the eye or cloudiness of the eye surface, death of eye surface cells, perforation, and permanent loss of vision; these effects may be delayed for 12 hours or more (ATSDR 1999; ATSDR 2010).

Salon Indoor Air Concentrations

Multiple studies have noted the presence of formaldehyde in the indoor air of hair salons (Table 1), in some cases, at concentrations two to three times OSHA limits (OSHA 2012). Hadei et al. (2018) found that concentrations of formaldehyde in indoor air were higher than in outdoor air, indicating that salon products were the source and not natural sources.

Study	Minimum Concentration	Maximum Concentration	
Hadei et al. (2018) n = 20	4.91 μg/m³ (0.004 ppm)	25 μg/m ³ (0.020 ppm) (30-minute period)	
Asare-Donkor et al. (2020) n = 60	21 μg/m³ (0.017 ppm)	434 μg/m ³ (0.353 ppm) (30-minute period)	
Oregon OSHA (2010) n =7	270 μg/m ³ (0.220 ppm)	2,310 μg/m ³ (1.88 ppm) (13–26-minute period)	
Pierce et al. (2011) n = 16	98 μg/m³ (0.080 ppm)	4,260 μg/m ³ (3.47 ppm) (6-16-minute period)	
OSHA (2011b) n = 3	3070 μg/m³ (2.5 ppm)	12,280 μ g/m ³ (10.0 ppm) (15-minute period)	

Table 1 Detections of Formaldehyde Concentrations in Hair Salon Indoor Air

From 2010-2012, OSHA cited 40 hair salons and beauty schools in the U.S. for failing to meet formaldehyde safety standards, failing to test air concentrations, and/or exceeding 15-minute exposure level periods (OSHA 2012). The number of cases brought by OSHA may not reflect the true magnitude of the problem. Two other organizations concerned with occupational health— the National Institute for Occupational Safety and Health (NIOSH) and the American Conference of Governmental Industrial Hygienists (ACGIH)—both recommend much lower limits for formaldehyde exposure in the workplace than those adopted by OSHA (NIOSH 2019; ACGIH 2022). A comparison of OSHA's limits for concentrations of formaldehyde in the air and ACGIH and NIOSH recommendations are presented in Table 2.

Table 2 OSHA Limits Versus Others' Recommendations

Agency	Daily (For a 40-hour work week)	Short-term (15-minute period)
OSHA permissible exposure limit	921 μg/m ³ (0.75 ppm) PEL-TWA ²	2,456 μg/m³ (2.0 ppm)
(PEL) (OSHA 2023a)	(8-hour period)	PEL-STEL ³
NIOSH recommended exposure	19.65 μg/m³ (0.016 ppm) REL-TWA	122.8 μg/m³ (0.1 ppm)
limit (REL) (NIOSH 2019)	(up to a 10-hour period)	REL-C ⁴
ACGIH threshold limit value (TLV)	122.8 μg/m³ (0.1 ppm) TLV-TWA (8-	368.4 μg/m³ (0.3 ppm)
(ACGIH 2022)	hour period)	TLV-STEL

Adverse Impacts

Reports made to the Food and Drug Administration (FDA) and obtained by the Environmental Working Group (EWG) highlight the adverse health reactions that can result from formaldehyde exposure (EWG 2021). From 2011 to 2019, FDA received 84 adverse effect reports from salon professionals, consumers, and bystanders who were present when hair treatments containing or releasing formaldehyde were used (FDA 2020a; FDA 2020b; FDA 2020c; FDA 2020d). Those reporting adverse health effects ranged in age from 14 to 69, and most were female. Reported health effects varied in severity, with the most-stated effects being general formaldehyde poisoning, hair loss, burning and itching of skin and body parts, neurological issues, breathing problems, allergic reactions, headaches, nose bleeds, eye damage, and pain throughout the body. Less commonly reported health effects included acute myeloid leukemia, inflamed liver, alopecia, and a metallic taste in the mouth.

In addition to reports from consumers, several epidemiological studies have found links between exposure to formaldehyde in hair straighteners and adverse health impacts, including to children.

² TWA is Time-weighted Average

³ STEL is Short-term Exposure Limit

⁴ C is Ceiling

Couto et al. (2013) found possible associations between the use of hair dyes and hair straightening products during pregnancy and the development of leukemia in children under two. Another study looked at formaldehyde exposures during pregnancy and kidney problems among their children. Shrestha et al. (2014) found positive associations between a cancer of the kidney, Wilms' tumor, and formaldehyde exposure during the third trimester of pregnancy. In a clinical case study of one child, Mitler et al. (2021) described acute kidney injury in a 13-year-old girl after exposure to formaldehyde in a hair straightening product labeled as "formaldehyde-free."

As mentioned previously, women of African descent use hair straightening products more commonly than do women of other races or ethnicities. The Black Women's Health Study followed more than 44,000 Black women over 22 years and found that postmenopausal women who were long-term users of hair relaxers were more likely to develop uterine cancer (Bertrand et al. 2023). Similarly, the Sister Study followed more than 33,000 women over 10 years and found that individuals who reported using hair straightening products in the past 12 months were more likely to have uterine cancer, and this association was stronger with more frequent usage (Chang et al. 2022).

Clarke et al. (2022) also found higher mortality rates from uterine cancer among women of African descent relative to women of other races and ethnicities, and that the rate has been increasing significantly over time; the study did not explore the use of hair straightening products but indicates that the factors they did look into were not enough to explain this discrepancy. The largest mortality rate increases were for Hispanic women, followed by Black women, and Asian or Pacific Islander women (Clarke et al. 2022). Although Black women represented a smaller percent of uterine cancer diagnoses from 2010 to 2017, they experienced the highest mortality rates, even when cancer subtype and stage at diagnosis were considered (Clarke et al. 2022). For newly diagnosed cases of uterine cancer, the mortality rate among Black women was two to three times higher than women of other races and ethnicities (Clarke et al. 2022).

5. RATIONALE FOR PURSUING NO FURTHER ACTION

Despite our significant concern about the continued use of formaldehyde and other chemicals in hair straightening products that release formaldehyde, we have decided <u>not</u> to pursue a Priority Product listing for formaldehyde in hair straightening products because other measures will soon be in place to address their risks. Since we first began researching this product-chemical combination, numerous other plans to regulate formaldehyde in hair straightening products have been announced.

In September 2020, California Governor Gavin Newsom signed the Toxic-Free Cosmetics Act into law (HSC 108980). Beginning in 2025, this law will prohibit 24 chemicals (including formaldehyde and methylene glycol) in beauty and personal care products sold in California. Specific ingredients related to this law include formaldehyde (CAS No. 50-00-0), paraformaldehyde (CAS No. 30525-89-4), methylene glycol (CAS No. 463-57-0), and quaternium 15 (CAS no. 51229-78-8). The Toxic-Free

Cosmetics Act aims to align California's regulations with those of the European Union. Through the European Cosmetics Directive (EC 1223/2009), formaldehyde is listed as a banned substance, and any products that contain or release formaldehyde must contain a warning on the label. Additionally, FDA has proposed a ban on formaldehyde and formaldehyde-releasing chemicals (including methylene glycol) as ingredients in hair straightening products or hair smoothing products. If this rule is approved, it would apply to all products sold in the U.S. (HHS/FDA 2023).

The Toxic-Free Cosmetics Act and other proposed rules will ban formaldehyde in hair straightening products. Therefore, there is no longer a need for this product-chemical combination to be listed as a Priority Product. Our decision is in line with the Safer Consumer Products (SCP) Regulations, Title 22, section 69503.2 of the California Code of Regulations, which states that we should not duplicate existing regulations unless doing so would meaningfully enhance how the product-chemical combination is regulated (22 CCR 69503.2).

6. INADEQUATE ALTERNATIVES

Consumers and businesses may face barriers in identifying truly formaldehyde-free products, as we are aware of products marketed as alternatives to formaldehyde-based hair straightening products that may be of concern. In some cases, products labeled as "organic," "natural," or "formaldehyde-free" have been found to contain formaldehyde⁵ (NYSDOH 2011).

Other products labeled as formaldehyde-free may contain formaldehyde releasers, including chemicals that are not affected by the Toxic-Free Cosmetics Act ban and are not explicitly addressed by the FDA's proposed ban. For example, cross-linking alternative hair straightening treatments have been called into question due to their potential to release formaldehyde (EWG 2011). Appendix A provides a more extensive list of chemicals that may release formaldehyde when mixed or heated, however we have not evaluated whether each of these chemicals release formaldehyde or the potential for concern associated with the use of these chemicals in hair straightening products. An additional concern involves labeling requirements. The Fair Packaging and Labeling Act only requires ingredients to be listed on cosmetics sold to consumers and not on those sold to businesses (CFR 16 502). However, the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) (HR 2617) will now require labeling for cosmetic products sold to businesses, allowing salon owners and hair stylists to make more informed decisions about the products they buy and use on their customers.

⁵ Sale of formaldehyde-containing cosmetic products in California without disclosing the ingredients to the California Department of Public Health (CDPH) is already a violation of the Cosmetic Fragrance and Flavor Ingredient Right to Know Act of 2020 (CFFIRKA) and sale of these products will be prohibited altogether when the Toxic-Free Cosmetics Act takes effect in 2025.

7. CONCLUSION

While statutory action within California has limited SCP's ability to contribute to the regulation of formaldehyde in hair straightening products, we continue to evaluate other chemicals of concern in these products. We remain committed to making consumer products safer, and we hope you will join us on this journey. We welcome new information, research, feedback, and suggestions for any other chemicals, products, or product-chemical combinations relating to this decision document.

ACRONYMS AND ABBREVIATIONS

µg/m³	micrograms per cubic meter
ACGIH	American Conference of Governmental Industrial Hygienists
ATSDR	Agency for Toxic Substances and Disease Registry
BLS	U.S. Bureau of Labor Statistics
CIR	Cosmetic Ingredient Review
DTSC	Department of Toxic Substances Control
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
EWG	Environmental Working Group
FDA	Food and Drug Administration
FPLA	Fair Packaging and Labeling Act
IARC	International Agency for Research on Cancer
NIOSH	National Institute for Occupational Safety & Health
NTP	National Toxicology Program
OEHHA	Office of Environmental Health Hazard Assessment
OSHA	Occupational Safety and Health Administration
ppm	parts per million
SCP	Safer Consumer Products
STEL	Short-term Exposure Limit
TWA	Time-weighted Average

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8. APPENDIX A: OTHER CHEMICALS THAT MAY RELEASE FORMALDEHYDE

Some sources indicate that the following chemicals may release formaldehyde (McConnell 2016; CARB 2020; OSHA 2023b). However, we have not evaluated whether each of these chemicals release formaldehyde, or the adverse impacts associated with the use of these chemicals in hair straightening products:

- (phenylmethoxy)methanol
- 1,3,5,7-tetraazatricyclo(3.3.1.1) decane
- 1,3,5-triazine-1,3,5(2H,4H,6H)-triethanol
- 1,3-bis(hydroxymethyl)-5,5-dimethyl-2,4-imidazolidinedione
- 1-hydroxymethyl-5,5-dimethyl-2,4-imidazolidinedione
- 2-(hydroxymethyl)-2-nitro-1,3-propanediol
- 2-(hydroxymethylamino)ethanol
- 2,4-imidazolidinedione
- 2-bromo-2-nitro-1,3-propanediol
- 2-chloro-N-(hydroxymethyl)-acetamide
- 3,3'-methylenebis(5-methyloxazolidine)
- 3-hydroxymethyl-5,5-dimethyl-2,4-imidazolidinedione
- 5-bromo-5-nitro-1,3-dioxane
- 5-bromo-5-nitro-1,3-dioxane
- 7a-ethyldihydro-1H, 3H,5H-oxazolo[3,4-c]oxazole
- bronopol (2-bromo-2-nitropropane-1,3-diol)
- cyclopentasiloxane
- diazolidinyl urea
- dimethicone
- dimethoxymethane
- DMDM hydantoin
- formaldehyde polymer with dimethyl-2,4-imidazolidinedione
- glyoxylic acid
- glyoxyloyl carbocysteine
- hydroxymethly-5,5-dimethyl-2,4-imidazolidinedione
- hydroxymethylglycinate
- imidazolidinyl urea
- Mixture of: 1,3,5-triethylhexahydro-1,3,5-triazine and 1,3,5-triazine-1,3,5(2H,4H,6H) triethanol
- Mixture of: 4-(2-nitrobutyl)morpholine and 4,4'-(2-ethyl-2-nitro-1,3-propanediyl)bismorpholine
- N-(1,3-bis(hydroxymethyl)2-5-dioxo-4-imidiazolidinyl)-N,N'-bis(hydroxymethyl)urea
- N-(3-chloroallyl)hexamethylene-tetraminiumchloride
- N,N'-bis(hydroxymethyl)urea
- N,N"-methylenebis(N'-(3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl)urea)
- phenyl trimethicone
- timonacic acid

9. APPENDIX B: REPORT PREPARATION

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