

Focus on Women's Health



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FDA Warns That Most Hair Smoothing or Straightening Products Release Formaldehyde Gas During the Hair Straightening or Smoothing Process

On March 2, 2021, the U.S. Food & Drug Administration (“FDA”) issued a consumer update in the form of a “what you should know” regarding formaldehyde in hair smoothing or straightening products, such as keratin treatments.¹ FDA cautions that certain hair smoothing or straightening products may release formaldehyde gas into the air once heat is applied to the hair with a flat iron or other similar tool.² Prior to 2004, certain studies concluded that formaldehyde was “probably” or “possibly” carcinogenic.³ Since that time, formaldehyde has been classified as a human carcinogen by both the International Agency for Research on Cancer (“IARC”) in 2004⁴ and later the U.S. Environmental Protection Agency (“EPA”) in 2010.⁵ Specifically, IARC placed formaldehyde in Group 1, along with alcoholic beverages, processed meats, salted fish, and other mixtures where the evidence of carcinogenicity in humans was insufficient to merit a more heightened classification.⁶ Similarly, the EPA classified formaldehyde as a “probable human carcinogen, based on limited evidence in humans.”⁷

While FDA regulates cosmetics, it does not have authority over the practice of cosmetology or how hair salons operate—workplace safety, including air quality, is governed by the Occupational Safety and Health Administration (“OSHA”).⁸ In September 2011, OSHA issued a Hazard Alert Update highlighting its continuing investigative work into hair smoothing products that were falsely labeled “formaldehyde free” or improperly omitted formaldehyde on the product label.⁹ Specifically, if a product contains 0.1% or more formaldehyde or can release formaldehyde into the air above 0.1 parts per million (ppm), then an



employer must take certain steps, as required by OSHA's Formaldehyde Standard, 29 CFR 1910.1048(m)(2)(ii), to warn its employees.

Historically, as far back as 2011, FDA has issued warning letters to manufacturers of hair straightening products that failed to warn of health risks stemming from formaldehyde. With this recent alert, it is clear FDA remains actively engaged in regulating this space and continuing its commitment to focus on women's health issues.

In this latest consumer update, FDA warns consumers that formaldehyde exposure above 0.1 ppm can cause a broad range of both short-term health effects, such as eye irritation, headaches, dizziness, various respiratory issues, nausea, chest pain, vomiting, rashes, and more chronic issues like frequent headaches, asthma, contact dermatitis, and potentially, cancer.¹⁰ Namely, FDA discourages consumers from buying or using smoothing hair products for *home use* that contain formaldehyde, formalin, and methylene glycol, and instead urges consumers to go to licensed hair professionals trained in the proper safety precautions to limit exposure.¹¹ If consumers nonetheless consider applying these products themselves, FDA advises that they use products *without* formaldehyde as a listed ingredient.¹²

This heightened public awareness and scrutiny by FDA of hair smoothing/straightening products may signal increased litigation risks for product manufacturers. Ultimately, manufacturers whose products contain formaldehyde can engage in best practices by ensuring their affected products contain proper labeling and warnings; considering providing product use trainings for professionals, as needed; and continuing to research safe, effective product formulations and application methods.

¹ FDA, CONSUMER UPDATES, FORMALDEHYDE IN HAIR SMOOTHING PRODUCTS: WHAT YOU SHOULD KNOW (MAR. 2, 2021), [HTTPS://WWW.FDA.GOV/CONSUMERS/CONSUMER-UPDATES/FORMALDEHYDE-HAIR-SMOOTHING-PRODUCTS-WHAT-YOU-SHOULD-KNOW?UTM_MEDIUM=EMAIL&UTM_SOURCE=GOVDELIVERY](https://www.fda.gov/consumers/consumer-updates/formaldehyde-hair-smoothing-products-what-you-should-know?utm_medium=email&utm_source=govdelivery).

² *Id.*

³ KENNETH A. MUNDT, ET AL., *SIX YEARS AFTER THE NRC REVIEW OF EPA'S DRAFT IRIS TOXICOLOGICAL REVIEW OF FORMALDEHYDE: REGULATORY IMPLICATIONS OF NEW SCIENCE IN EVALUATING FORMALDEHYDE LEUKEMOGENICITY*, REGULATORY TOXICOLOGY AND PHARMACOLOGY 92 (2018) 472–490474 (2017), AVAILABLE AT [HTTPS://READER.ELSEVIER.COM/READER/SD/PII/S027323001730363X?TOKEN=0B9B35861A79E7DBF15423051DCF13325ADB4EC0F7524FB33BD1348094D7779D601711FDE6DB3A9E7CD2837A10880F71](https://reader.elsevier.com/reader/sd/pii/S027323001730363X?token=0B9B35861A79E7DBF15423051DCF13325ADB4EC0F7524FB33BD1348094D7779D601711FDE6DB3A9E7CD2837A10880F71).

⁴ IARC. IARC MONOGRAPHS ON THE EVALUATION OF THE CARCINOGENIC RISKS TO HUMANS FORMALDEHYDE, 2-BUTOXYETHANOL AND 1-TERT-BUTOXYPROPAN-2-OL, VOL. 88, WORLD HEALTH ORGANIZATION (WHO); INTERNATIONAL AGENCY FOR RESEARCH ON CANCER, LYON, FRANCE (2006).

⁵ EPA, TOXICOLOGICAL REVIEW OF FORMALDEHYDE - INHALATION ASSESSMENT (JUNE 2, 2010) (CAS NO. 50-00-0), [HTTPS://OFMPUB.EPA.GOV/EIMS/EIMSCMM.GETFILE?P_DOWNLOAD_ID=497038](https://ofmpub.epa.gov/eims/eimscmm.getfile?p_download_id=497038).

⁶ IARC, MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISK FOR HUMANS, FORMALDEHYDE, AVAILABLE AT [HTTPS://MONOGRAPHS.IARC.WHO.INT/WP-CONTENT/UPLOADS/2018/06/MONO88-6.PDF](https://monographs.iarc.who.int/wp-content/uploads/2018/06/MONO88-6.pdf).

⁷ EPA, INTEGRATED RISK INFORMATION SYSTEM (IRIS), CHEMICAL ASSESSMENT SUMMARY, FORMALDEHYDE; CASRN 50-00-0, AVAILABLE AT [HTTPS://CFPUB.EPA.GOV/NCEA/IRIS/IRIS_DOCUMENTS/DOCUMENTS/SUBST/0419_SUMMARY.PDF#NAMEDDEST=WOE](https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0419_summary.pdf#nameddest=woe).

⁸ OSHA, HAIR SALONS: FACTS ABOUT FORMALDEHYDE IN HAIR PRODUCTS (LAST ACCESSED ON MARCH 26, 2021), AVAILABLE AT [HTTPS://WWW.OSHA.GOV/HAIR-SALONS](https://www.osha.gov/hair-salons).

⁹ OSHA, HAZARD ALERT UPDATE (SEPTEMBER 2011), AVAILABLE AT [HTTPS://WWW.OSHA.GOV/SITES/DEFAULT/FILES/HAZARD_ALERT.PDF](https://www.osha.gov/sites/default/files/hazard_alert.pdf).

¹⁰ FDA, CONSUMER UPDATES, FORMALDEHYDE IN HAIR SMOOTHING PRODUCTS: WHAT YOU SHOULD KNOW (MAR. 2, 2021), [HTTPS://WWW.FDA.GOV/CONSUMERS/CONSUMER-UPDATES/FORMALDEHYDE-HAIR-SMOOTHING-PRODUCTS-WHAT-YOU-SHOULD-KNOW?UTM_MEDIUM=EMAIL&UTM_SOURCE=GOVDELIVERY](https://www.fda.gov/consumers/consumer-updates/formaldehyde-hair-smoothing-products-what-you-should-know?utm_medium=email&utm_source=govdelivery).

¹¹ FDA, COSMETICS FACTS, WHAT CONSUMERS SHOULD KNOW ABOUT HAIR SMOOTHING PRODUCTS AND FORMALDEHYDE (JAN. 2021), AVAILABLE AT [HTTPS://WWW.FDA.GOV/MEDIA/146213/DOWNLOAD](https://www.fda.gov/media/146213/download).



¹² FDA, CONSUMER UPDATES, FORMALDEHYDE IN HAIR SMOOTHING PRODUCTS: WHAT YOU SHOULD KNOW (MAR. 2, 2021), [HTTPS://WWW.FDA.GOV/CONSUMERS/CONSUMER-UPDATES/FORMALDEHYDE-HAIR-SMOOTHING-PRODUCTS-WHAT-YOU-SHOULD-KNOW?UTM_MEDIUM=EMAIL&UTM_SOURCE=GOVDELIVERY](https://www.fda.gov/consumers/consumer-updates/formaldehyde-hair-smoothing-products-what-you-should-know?utm_medium=email&utm_source=govdelivery).

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