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Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION FOR REGULATORY ACTION TO)
ADDRESS SAFETY CONCERNS SURROUNDING)
KERATIN HAIR-STRAIGHTENERS THAT CONTAIN)
FORMALDEHYDE AND FORMALDEHYDE-)
RELEASING CHEMICALS AS INGREDIENTS)

Via Federal Express
By the Environmental Working Group

CITIZEN PETITION

Environmental Working Group (EWG) hereby submits this citizen petition to the Commissioner of the U.S. Food and Drug Administration (FDA) under the federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301-399, and the Administrative Procedure Act (APA), 5 U.S.C. § 553(e). EWG requests that FDA take regulatory action to respond to the mounting health concerns surrounding the manufacturing, labeling, and marketing of keratin hair-straighteners shown to release formaldehyde during the treatment process.

I. INTRODUCTION

EWG is a non-partisan, non-profit organization dedicated to using the power of information to protect public health and the environment. EWG provides resources to consumers such as the Skin Deep Cosmetic Safety Database and advocates policies that promote conservation and mitigate health risks.

In keeping with those aims, EWG continues to monitor reports from Oregon's Occupational Health and Safety Division (Oregon OSHA) regarding the discovery of formaldehyde in Brazilian Blowout, a popular keratin hair-straightener once promoted as "formaldehyde free."¹

¹ Press Release, Or. Health & Sci. Univ. Ctr. for Research on Occupational and Env'tl. Toxicology, OHSU Toxicology Center Issues Public Alerts About the Ingredients of a Popular Hair Salon Treatment (Sept. 30, 2010), http://www.orosha.org/admin/newsrelease/2010/nr2010_24.pdf.

According to Oregon OSHA, health officials found formaldehyde levels in Brazilian Blowout that were more than 50 times industry's recommended limit.² They conducted tests after receiving complaints from hairstylists who reportedly experienced eye irritation, nosebleeds, and difficulty breathing after using the product.³

In February 2011, months after the Oregon OSHA announcement, Brazilian Blowout unveiled "Brazilian Blowout Zero" as a formaldehyde-free alternative to its original "formaldehyde free" solution.⁴ The company also scrubbed claims regarding formaldehyde from the original solution bottle and online product information.⁵ EWG contacted Brazilian Blowout to inquire about the changes on February 24, 2011.⁶ EWG was told by a Brazilian Blowout representative that the company had "a bit of a labeling issue" with the original solution because it in fact releases formaldehyde during the treatment process.⁷ However, the representative maintained that Brazilian Blowout has never used formaldehyde as an ingredient, indicating that the company continues to make a spurious distinction between formaldehyde and formaldehyde in solution, which reversibly forms methylene glycol until exposed to air.⁸

EWG continues to be troubled by the Brazilian Blowout imbroglio because it shows how cosmetic companies might use deception to impose significant health risks on the public. After all, formaldehyde can cause severe allergic reactions and respiratory problems such as those experienced by the Oregon stylists.⁹ Furthermore, medical experts largely believe that formaldehyde is a human carcinogen.¹⁰

As EWG suspected, the Brazilian Blowout story is hardly an isolated event. In fact, EWG has identified at least 12 other manufacturers that appear to be hiding whether their hair-straighteners release formaldehyde during the treatment process.¹¹ In response, EWG asks FDA to investigate the marketing and labeling practices of these companies and confirm whether their products release the chemical at levels reported by various health agencies. EWG also asks FDA to require warning labels for hair-straighteners with formaldehyde, including formaldehyde in solution, and/or formaldehyde-releasing chemicals to highlight the risk of exposure. Finally, EWG requests that FDA review whether to ban formaldehyde and formaldehyde-releasing chemicals from these products given the significant health hazard they pose to consumers.

² See *id.*; see also *Cosmetic Ingredient Rev., 2009 CIR Compendium* 83 (2009).

³ Andrea Canning, et al., *Brazilian Blowout Hair-Straightening Product Under Fire*, ABC News, Oct. 1, 2010, <http://abcnews.go.com/GMA/Consumer/brazilian-blowout-hair-straightening-samples-formaldehyde/story?id=11771569>.

⁴ *Brazilian Blowout Zero*, <http://www.brazilianblowout.com/zero> (last visited Feb. 23, 2011).

⁵ See Ex. B at 11-12.

⁶ *Infra* III.1.B.x.

⁷ *Id.*

⁸ *Infra* III.1.A.i; see also *infra* III.1.B.

⁹ *Infra* III.1.A.ii.

¹⁰ *Id.*

¹¹ *Infra* III.1.B.

II. ACTIONS REQUESTED

1. Investigate and respond appropriately to the deceptive practices of companies that conceal the fact that their hair-straighteners release formaldehyde under customary conditions of use, pursuant to 21 U.S.C. §§ 331(a), 362(a), 321(n), 336, 374, 375(b), 371(a), and 21 C.F.R. §§ 1.21, 7.40(b);
2. Require labels for hair-straighteners that contain formaldehyde, including formaldehyde in solution, and formaldehyde-releasing chemicals that warn users about the risk of exposure during the treatment process, pursuant to 21 U.S.C. §§ 331(a), 361(a), 362(a), 321(n), 371(a), and 21 C.F.R. § 740.1; and
3. Review whether to ban the use of formaldehyde, including formaldehyde in solution, and formaldehyde-releasing chemicals as ingredients in hair-straighteners, pursuant to 21 U.S.C. §§ 331(a), 361(a), and 371(a). Please note that EWG strongly urges FDA to prohibit the use of formaldehyde and formaldehyde-releasing chemicals in hair-straighteners. Yet FDA's environmental assessment regulations for petitioners, 21 C.F.R. §§ 10.30, 25.30, are so onerous that EWG must limit its request to a FDA review of whether a ban is appropriate.

III. STATEMENT OF GROUNDS

1. Factual Grounds

A. Formaldehyde, Formaldehyde-Releasing Chemicals, and Hair-Straighteners Containing Such Ingredients Constitute Clear Health Hazards to Consumers

i. Formaldehyde's Chemical Properties and Use in Products such as Keratin Hair-Straighteners

Formaldehyde is “a flammable, colorless gas with a pungent, suffocating odor.”¹² The chemical occurs naturally, at least in small amounts,¹³ but has been commercially produced for more than a century.¹⁴ Formaldehyde “is unstable in its pure, gaseous state.”¹⁵ Yet because it is water-soluble,¹⁶ most suppliers distribute the chemical in “an aqueous solution” where it is “almost

¹² U.S. Agency for Toxic Substances & Disease Registry, Formaldehyde CAS # 50-00-0 ToxFAQs 1 (2008), www.atsdr.cdc.gov/tfacts111.pdf [hereafter ATSDR, Formaldehyde]; see also Int'l Agency for Research on Cancer, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Formaldehyde, 2-Butoxyethanol and 1-tert-Butoxypropan-2-ol 39 (2006), <http://monographs.iarc.fr/ENG/Monographs/vol88/mono88.pdf> [hereafter IARC, Formaldehyde].

¹³ ATSDR, Formaldehyde, *supra* note 12, at 1.

¹⁴ IARC, Formaldehyde, *supra* note 12, at 43.

¹⁵ J.G.M. Winkelman, et al. Kinetics and Chemical Equilibrium of the Hydration of Formaldehyde, 57 Chem. Eng'g Sci. 4067 (2002).

¹⁶ Shen Dong & Purnendu K. Dasgupta, Solubility of Gaseous Formaldehyde in Liquid Water and Generation of Trace Standard Gaseous Formaldehyde, 20 *Envtl. Sci. Tech.* 637 (1986).

completely hydrated [in]to methylene glycol.”¹⁷ Formaldehyde will remain in that convenient, aqueous state until exposed to air, at which point formaldehyde gas is released.¹⁸

Manufacturers primarily use the chemical to produce “paper, plywood, and [certain] resins.”¹⁹ However, companies also use formaldehyde as a component in certain cosmetic products, including keratin hair-straighteners, because of its ability to cross-link proteins found in hair.²⁰

ii. Formaldehyde Linked to Substantial Short- and Long-Term Health Risks

Scientists have documented in great detail the health risks associated with formaldehyde exposure. Short-term effects may include “eye, nose and throat irritation, loss of sense of smell, increased upper respiratory disease, dry and sore throats, respiratory tract irritation, cough, chest pain, shortness of breath and wheezing.”²¹ Exposure also can cause “skin irritation and allergic dermatitis as a result of skin contact with water solutions of formaldehyde.”²² As for long-term effects, the U.S. Agency for Toxic Substances and Disease Registry (ATSDR) and the International Agency for Research on Cancer (IARC) classify formaldehyde as a human carcinogen.²³ Likewise, the U.S. Occupational Safety and Health Administration (OSHA) states that formaldehyde can be “reasonably anticipated” to be a “human carcinogen [that] has been linked to nasal and lung cancer, with possible links to brain cancer and leukemia.”²⁴ The U.S. Environmental Protection Agency (EPA) largely affirms those positions, noting that formaldehyde has “been shown to cause cancer in animals and may cause cancer in humans.”²⁵ Finally, in addition to its carcinogenicity, formaldehyde is suspected of having certain “neurological effects,” increasing the “risk of asthma,” and causing “eczema and changes in lung function.”²⁶ Thus, FDA should have serious reservations about permitting formaldehyde’s use in

¹⁷ Winkelman, *supra* note 15, at 4067.

¹⁸ Or. OSHA & Or. Health & Sci. Univ. Ctr. for Research on Occupational and Env'tl. Toxicology, ‘Keratin-Based’ Hair Smoothing Products and the Presence of Formaldehyde 13 (2010), www.orsosha.org/pdf/Final_Hair_Smoothing_Report.pdf [hereafter Or. OSHA Report].

¹⁹ ATSDR, Formaldehyde, *supra* note 12, at 1.

²⁰ E.g., Wool: Science and Technology 152-53 (W.S. Simpson & G.H. Crawshaw eds., 2002); see also Cosmetic Ingredient Rev., Draft Amended Report: Formaldehyde and Methylene Glycol 4 (2011), http://www.cir-safety.org/staff_files/form.pdf [hereafter CIR, Formaldehyde and Methylene Glycol] (“known to induce a fixative action on proteins”).

²¹ Or. OSHA Report, *supra* note 18, at 10.

²² *Id.* (based on “many reports” cited by National Institute for Occupational Safety and Health).

²³ ATSDR, Formaldehyde, *supra* note 12, at 2 (“based on human and animal inhalation studies”); see also IARC, Formaldehyde, *supra* note 12, at 280.

²⁴ OSHA, Safety and Health Topics: Formaldehyde, <http://www.osha.gov/SLTC/formaldehyde/index.html> (citing HHS, Report on Carcinogens (11th ed. 2005)) (last visited Mar. 8, 2011).

²⁵ EPA, An Introduction to Indoor Air Quality (IAQ): Formaldehyde, <http://www.epa.gov/iaq/formalde.html#Health%20Effects> (last visited Mar. 8, 2011).

²⁶ ATSDR, Formaldehyde, *supra* note 12, at 1.

cosmetics, particularly given the fact that keratin hair-straighteners release the chemical where users can readily inhale its fumes.²⁷

iii. FDA Adverse Event Reports Evidence Numerous Injuries Sustained By Users of Keratin Hair-Straighteners

The risks associated with keratin hair-straighteners said to release formaldehyde are more than theoretical considerations. In fact, FDA has received at least 47 adverse event reports about these products since 2008, according to records obtained in response to several Freedom of Information Act (FOIA) requests.²⁸ The details of those reports are as follows:

- “[T]he smell from the product caused her eyes to burn[.] The smell caused two hairstylists to have breathing problems and one of them had to leave work[.] One man at the salon got a headache and also had to leave[.]”
 - Complaint about “Brazilian Blow-out” reported on May 18, 2009²⁹;
- “[The] person experienced headaches, dizziness, and blurred vision[.]”
 - Complaint about “Brazilian Keratin Treatment” reported on Mar. 12, 2010³⁰;
- “Salon owner reports [that] her hair stylists using Brazilian Blowout Hair Straightener and Conditioning Lotion products are becoming ill from the strong formaldehyde fumes[.] Some of the stylists and [a] few customers developed respiratory symptoms, persistent coughs, headaches, [and] eye irritation[.] Complainant attempted to obtain [an] ingredient list from [the] company but was refused . . . This complaint is the latest of four calls [received] at FDA pertaining to Brazilian Blowout since [May 8, 2009.]”
 - Complaint about “Brazilian Blowout/Hair Treatment” and “Ultrasmooth/Blowout Lotion” reported on Mar. 26, 2010³¹;

²⁷ In 2005 the Cosmetic Ingredient Review (CIR) concluded that formaldehyde should not exceed 0.2 percent when used in cosmetic products. CIR, Cosmetic Ingredient Review: Final Report on the Safety of Formaldehyde 1 (2006); see also Press Release, Personal Care Products Council, Statement by John Bailey, Chief Scientist, Personal Care Products Council: Industry Concerned About Safety of Ingredient in Professional Hair Smoothing Products (Nov. 4, 2010), <http://www.personalcarecouncil.org/newsroom/20101104>. When conducting its assessment, CIR primarily focused on formaldehyde’s use as a preservative and not as a binding agent in hair-straighteners. *Id.* For that reason, CIR continues to hold that it “cannot [] conclude [] that formaldehyde is safe in cosmetic products intended to be aerosolized.” *Id.* Moreover, a tentative CIR report from March 9, 2011, indicates that CIR cannot identify a safe exposure level for cosmetics that emit formaldehyde/methylene glycol vapor or gas such as certain keratin hair-straighteners. See Announcement, CIR, Cosmetic Ingredient Review Expert Panel 118th Meeting (March 3-4, 2011) – Findings (Mar. 9, 2011), http://www.cir-safety.org/staff_files/results.pdf (“It cannot be concluded that formaldehyde/methylene glycol is safe in cosmetic products intended to be aerosolized or in which formaldehyde/methylene glycol vapor or gas will be produced under conditions of use.”).

²⁸ Ex. A (contains copy of FDA adverse event reports for keratin hair-straighteners since 2008 with checkmarks added by EWG staff when processing contents).

²⁹ Ex. A at 4.

³⁰ *Id.* at 6.

- Complainant experienced “[h]air loss about the size of a silver doll[a]r on the temple[-] area of the head[.]”
 - Complaint about “Coppola/Keratin Complex” reported on Sept. 20, 2010³²;
- “During the blow drying process, the fumes and/or vapors which [are] emit[ted] into the air . . . are causing shortness of breath, chest pains, itchy and watery eyes[,] and a list of other symptoms such as rashes and fainting[.]”
 - Complaint about “Brazilian Blowout Solution Pro Treatment for Smoothing Hair” reported on Sept. 28, 2010³³;
- Complainant experienced “[w]atery eyes, breathing problems, [and] burning sensations[.]”
 - Complaint about “Brazilian Blowout Solution” reported on Sept. 29, 2010³⁴;
- “[Client] and her hairdresser both had a sever[e] reaction to the product. Both had burning eyes, burning nose[s], sore/raw throat[s][,] and [an] acute headache. . . . [The] MSDS for this product [does] not list any chemical agents[.]”
 - Complaint about “Brazilian Blowout” reported on Oct. 8, 2010³⁵;
- “The stylist just said to keep [my eyes] closed[.] Seemed like this had happened often – but it was extremely irritating and my eyes were burning/tearing even through closed eyes[.]”
 - Complaint about “Brazilian Blowout” reported on Oct. 8, 2010³⁶;
- “Each time I have experienced burning/running eyes and nose, headaches and [an] extremely raw and sore throat[.] I have contacted the company several times to question the adverse health effects that I and others experienced only to be told each time that the product is 100 percent formaldehyde free and safe[.]”
 - Complaint about “Brazilian Blowout” reported on Oct. 10, 2010³⁷;
- Complainant went to the “[h]ospital 2X, [after experiencing] dizziness, severe headaches, dermatitis, [and] sinus problems[.] . . . [Complainant’s] lungs [were] treated with [an] inhaler, [and Complainant was given] nasal spray, pain meds[.]”
 - Complaint about Coppola “Natural Keratin Smoothing Treatment” reported on Oct. 10, 2010³⁸;

³¹ Id.

³² Id. at 19.

³³ Id. at 9.

³⁴ Id. at 8.

³⁵ Id. at 28.

³⁶ Id. at 8.

³⁷ Id.

- “I’ve had nose bleeds, [a] very raw nose, difficulty breathing, pressure in [the] chest, [and] [my] eyes will not stop burning and coughing, which ha[ve] become progressively worse each time this product is used in the salon[.]”
 - Complaint about “The Brazilian Blowout” reported on Oct. 12, 2010³⁹;
- Product “[m]ade it hard [] to breathe while blow drying, [and] my eyes and my clients[’] eyes watered and burned[.] My co-worker broke out in[to] hives after applying[.]”
 - Complaint about “Brazilian Blowout” and “Strength Brazilian Blowout” reported on Oct. 13, 2010⁴⁰;
- “Complainant experienced scalp burn, [and] respiratory distress after hairdresser used Brazilian Blowout[.] Her sinuses, [and] ear canal [are in] pain[][.]”
 - Complaint about “Brazilian Blowout/Shampoo and Conditioner” reported on Oct. 15, 2010⁴¹;
- Complainant “experienced instant burn[ing] in [the] eye, sinus[es] and ear canal[,] [and] congestion upon initial exposure to [the] Brazilian Blowout hair[-]care product. . . . Complainant had [the] presence of blood whenever [her] nose [was] blown. . . . [and] symptoms including blepharitis, [which entails the] chronic inflammation of eyelids caused by backup in [the] meibomian gland[.]”
 - Complaint about “Brazilian Blowout” reported on Oct. 15, 2010⁴²;
- “[S]he becomes nauseous, dizzy, gets a sore throat, has a racing heart, double[-]vision, eyes burn[ing], gets a tightness in her chest, headache, fever[,] and has a lack of oxygen to the brain[.]”
 - Complaint about Coppola “Keratin Complex Smoothing Therapy” reported on Oct. 18, 2010⁴³;
- “Within five days of the treatment I began losing large amounts of hair, at least three-[to-]four times what I would usually lose in a day [or] in one month[.] I have experienced about a 40% volume loss in my hair and it continues to fall out at the same alarming pace[.]”
 - Complaint about “Brazilian Blowout Solution” reported on Oct. 18, 2010⁴⁴;

³⁸ Id. at 20.

³⁹ Id. at 7.

⁴⁰ Id. at 8.

⁴¹ Id. at 22.

⁴² Id. at 52.

⁴³ Id. at 32.

⁴⁴ Id. at 10.

- Complainant “experiences heart palpitations, lightheadedness, and burning in her eyes, nose and throat[.]”
 - Complaint about Coppola “Keratin Treatment & Express Blowout” reported on Oct. 19, 2010⁴⁵;
- “Complainant was told to not remove [Brazilian Blowout product applied after straightening] for 8 days until she return[ed] to the salon. After 2-3 days [Complainant noticed a] chemical odor and scalp pain became so unbearable she had to rinse her hair . . . [F]lu-like symptoms emerged, including headaches, [and] vomiting. . . . Clusters of her hair were also falling off. Complainant contacted salon owners to obtain [Brazilian Blowout] ingredients but was denied [them]. Complainant’s condition continued to deteriorate – persistent vomiting, difficulty breathing, [and] chest, eye and nose irritation developed. . . . Physician [diagnosed] her with severe head swelling, [and] hives. . . . Complainant also has COPD and controlled asthma which [the] chemical odor re-inflamed. . . . Complainant was admitted to [a facility] for respiratory distress. . . . [where she experienced] severe stability problems, [and] persistent vomiting. . . . Physician called poison control and was told that [Brazilian Blowout] did not contain any ‘harmful’ chemicals[.]”
 - Complaint about Brazilian Blowout “Hair Straightener” reported on Oct. 21, 2010⁴⁶;
- “I immediately experienced burning eyes, [a] burning and running nose and a burning throat. . . . I was in agony during and after the appointment[.] My eyes, especially the left one[.] continued to burn and I ended up at the optometrist[’]s office where I was diagnosed with an corneal abrasion[.]”
 - Complaint about “Brazilian Blowout” reported on Oct. 22, 2010⁴⁷;
- “I have had stinging watery eyes, headaches and nose burning from the fumes[.]”
 - Complaint about “Brazilian Blowout” reported on Oct. 22, 2010⁴⁸;
- “Immediate effects [include] burning of [the] scalp, exposed skin, eyes, nose, throat and chest, headache, [and a] tightness feeling to [the] chest like bronchial irritation[.]”
 - Complaint about American Culture Hair “Simply Smooth Keratin Treatment” reported on Oct. 22, 2010⁴⁹;

⁴⁵ Id. at 37.

⁴⁶ Id. at 41.

⁴⁷ Id. at 11.

⁴⁸ Id. at 13.

⁴⁹ Id. at 12.

- “The first time I used the product I could [] taste it in my throat and smell it for hours after the service[.] The second time I used the product my tongue was tingling and numb for a couple of hours and my eyes burned[.]”
 - Complaint about Global Keratin Xtremeon, USA “Global Hair Taming System with Juvexin” reported on Oct. 26, 2010⁵⁰;
- “After washing/rinsing [the] product out of her hair complainant immediately noted hair loss. . . . Over time [her] hair became thin and she experienced more hair los[s][.]”
 - Complaint about “Brazilian Blowout Solution Pro Treatment for Smoothing Hair” reported on Oct. 27, 2010⁵¹;
- “Complainant . . . developed headache, nausea, fatigue and anxiety symptoms whenever Brazilian Blowout [was] used at the salon.”
 - Complaint about “Brazilian Blowout” reported on Oct. 28, 2010⁵²;
- Complainant “[e]xperienced burning, stinging eyes and immediately gets a headache after he finishes the treatment[.]”
 - Complaint about “Brazilian Blowout/Hair Straightener” reported on Nov. 2, 2010⁵³;
- Complainant experienced a “[l]oss of taste and smell during the week she had a Brazilian Blowout[.]”
 - Complaint about “Brazilian Blowout” reported on Nov. 2, 2010⁵⁴;
- “I constantly now have headaches and my right eye does not stop watering. . . . I am nauseous every day[.]”
 - Complaint about “Brazilian Blowout Acai Anti-Frizz Shampoo” reported on Nov. 3, 2010⁵⁵;
- Complainant experienced “[s]ignificant eye irritation [and] headache[.]”
 - Complaint about “Brazilian Blowout” reported on Nov. 4, 2010⁵⁶;
- Complainant “[h]as experienced losing her voice, lung irritation, throat irritation, sinus irritation, skin irritation, headaches, and dizziness[.]”
 - Complaint about “Keratin Hair Treatment” reported on Nov. 5, 2010⁵⁷;

⁵⁰ Id.

⁵¹ Id. at 11.

⁵² Id. at 47.

⁵³ Id. at 21.

⁵⁴ Id. at 17.

⁵⁵ Id.

⁵⁶ Id.

- “During the time of my hair treatment, I experienced eye irritation and a bad smell[.]”
 - Complaint about Marcia Teixeira “Brazilian Keratin Treatment” reported on Nov. 5, 2010⁵⁸;
- “My hair started falling out and continues to do so[.] I have been to my dermatologist and he confirms that my hair follicles have been damaged[.]”
 - Complaint about “Brazilian Blowout – New Formula” reported on Nov. 5, 2010⁵⁹;
- “I did have noticeable eye irritation where I felt like my eyes were burning[.]”
 - Complaint about “Brazilian Blowout” reported on Nov. 7, 2010⁶⁰;
- “Hair continued to fall off as she continued to rinse. Blisters also [were] discovered on the back of [her] head. . . . [C]omplainant developed severe stability problems (severe dizziness). . . . Physician examined [her] and noted hair loss, blisters on [the] scalp and ulcer formation in her mouth.”
 - Complaint about “Brazilian Blowout/Hair Straightening & Conditioner” reported on Nov. 9, 2010⁶¹;
- Complainant “[e]xperienced burning eyes and requested [a] salon to open the door for better ventilation[.] Also [Complainant] experience[d] a funny taste sensation on [the] tongue during the process.”
 - Complaint about “Brazilian Blowout” reported on Nov. 10, 2010⁶²;
- “I am still symptomatic with nausea, stuffiness, fatigue, nas[a]l blockage, chest pain, [and] difficulty breathing[.]”
 - Complaint about “Brazilian Blowout” reported on Nov. 10, 2010⁶³;
- “Her eyes burn, her nose burns and she experienced nosebleeds, throat swellings, and headaches[.]”
 - Complaint about “Brazilian Blowout/Hair Straightener” reported on Nov. 12, 2010⁶⁴;

⁵⁷ Id. at 13.

⁵⁸ Id. at 17.

⁵⁹ Id. at 18.

⁶⁰ Id. at 16.

⁶¹ Id. at 13-14.

⁶² Id. at 19.

⁶³ Id. at 16.

⁶⁴ Id. at 15.

- “The complainant experienced headaches, eye irritation, and congested sinuses[.]”
 - Complaint about “Brazilian Blowout” and Coppola “Keratin Complex” reported on Nov. 17, 2010⁶⁵;
- Complainant experienced “hair loss[.] . . . The last treatment was done in July 2010, [and] caused massive hair loss[.]”
 - Complaint about “Peter Copolla Keratin Straightening Treatment” reported on Nov. 20, 2010⁶⁶;
- Complainant experienced “severe neck rashes, itching, welting, redness, [and] eventually [a] rash appeared on [the] sides of [the] face. . . . Upon application of hair product [Complainant] experienced severe eye[-]burning[.]”
 - Complaint about “Coppola Designer Hair Care/Keratin Complex” reported on Nov. 25, 2010⁶⁷;
- Complainant experienced “[d]rastically changed color of hair immediately and within a week had extreme hair loss which has not stopped[.]”
 - Complaint about Thomassen Beauty Supply “Pure NV BKT” reported on Dec. 1, 2010⁶⁸;
- “While my stylist was applying the solution to my hair my eyes started to burn, sting and tear excessively[.] My eyes remained red for the remainder of the day and I also was having persistent coughing fits[.]”
 - Complaint about “Brazilian Blowout Acai Straightener” reported on Dec. 1, 2010⁶⁹;
- “Within 10 minutes of application, my eyes stung so severely that I was tearing up[.] [] Within 10 minutes of application, I felt a very painful burning sensation in my nostrils. . . . That same evening I had a slight sore throat[.] [] The next morning, I had a very sore throat and red eyes[.]”
 - Complaint about “Brazilian Blowout” reported on Dec. 6, 2010⁷⁰;
- Product “[c]aused her to suffer shortness of breath, facial swelling, irritation to her eyes, nose and throat, throat damage, nasal discharge, sputum, sinus drainage, coughing, inhalation pneumonitis, bronchitis, hoarseness, memory problems, and fatigue[.]”
 - Complaint about “Brazilian Blowout Treatment” reported on Dec. 10, 2010⁷¹;

⁶⁵ Id.

⁶⁶ Id. at 20.

⁶⁷ Id.

⁶⁸ Id. at 22.

⁶⁹ Id.

⁷⁰ Id. at 23.

- “My scalp had been itching from the day I got the treatment and had become very dry. . . . My hair continued to break and fall out[.] I went back to the dermatologist and by this time my thick upper hair had a huge bald spot and I was given steroid injections[.]”
 - Complaint about “Keratin Express” reported on Dec. 13, 2010⁷²;
- Complainant “[e]xperienced headaches, burning throat and lungs, and nausea[.]”
 - Complaint about “Brazilian Blowout/Professional Products” reported on Dec. 21, 2010⁷³;
- “I had upper respiratory irritation symptoms, [a] head cold or so I thought[.] Th[e]n I began coughing and wheezing with che[s]t pain. . . . [I] was hospitalized with pneumonia[.]”
 - Complaint about “Brazilian Blowout Treatment + Shampoo, Conditioner, Serum and Masque” reported on Jan. 10, 2011⁷⁴; and
- “We did our own air quality test in the salon while doing a service[.] The lab just reported that there was the highest levels of formaldehyde they’ve ever seen in a product and it is potentially an extremely dangerous product if not used properly We have experienced short[-]term eye irritation, breathing problems, and headaches while doing the service and up to 12[hours] after[.] We are . . . concerned with the long[-]term health effects[.]”
 - Complaint about “Brazilian Blowout” reported on Nov. 9, 2010.⁷⁵

As these reports demonstrate, numerous keratin hair-straighteners on the market may generate adverse health effects as a consequence of use.⁷⁶ Moreover, many of the injuries described therein correspond to those associated with formaldehyde exposure, which is unsurprising in light of product tests by various health agencies. Accordingly, FDA should consider these products potential health hazards, a decision already reached by a number of other health agencies such as Health Canada⁷⁷ and the Irish Medicines Board.⁷⁸

⁷¹ Id. at 24.

⁷² Id. at 25.

⁷³ Id. at 26.

⁷⁴ Id. at 27.

⁷⁵ Id. at 18-19.

⁷⁶ The number of reports obtained by EWG likely represents a tiny fraction of the total adverse events generated by keratin hair-straighteners. See Dori Stehlin, Cosmetic Safety: More Complex Than at First Blush, FDA Consumer, Nov. 1991 (FDA estimates that it receives only about two percent of all adverse events reported to industry).

⁷⁷ See Press Release, Health Can., Brazilian Blowout Solution Contains Formaldehyde (Oct. 7, 2010), http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2010/2010_167-eng.php (“Health Canada is working with the exclusive Canadian distributor to address concerns regarding Brazilian Blowout Solution and to stop distribution of this product to salons in Canada.”) [hereafter Health Can., Brazilian Blowout].

⁷⁸ See Press Release, Irish Meds. Bd., Recall of Cosmetic Product Brazilian Blowout Acai Professional Smoothing Solution (Oct. 18, 2010) (copy included in Ex. C at 1) [hereafter Irish Meds. Bd., Recall].

B. Substantial Number of Companies Conceal Whether Their Products Release Formaldehyde When Applied to Consumers' Hair

As EWG highlights, more than a dozen companies use deception to hide or downplay the risk of formaldehyde exposure when using their keratin hair-straighteners. A number of the companies identified herein make false and misleading claims to suggest that their products are “formaldehyde free,” even though test results suggest otherwise. Other companies leave users in the dark by omitting material facts about formaldehyde exposure as a consequence of using such products.⁷⁹

To justify these practices, some companies peddle their own test results that rely on unconventional methods for analyzing formaldehyde content.⁸⁰ More common is for makers of keratin hair-straighteners to make a specious distinction between formaldehyde gas and formaldehyde in solution. Not only is such a distinction disingenuous, but it also lacks merit. As discussed above, formaldehyde exists in a gaseous state at room temperature, but is readily soluble in water.⁸¹ For that reason, suppliers often sell the chemical in solution form as “formalin”⁸² or “formaldehyde in solution.”⁸³ When in solution, formaldehyde reacts with water molecules and reversibly forms a compound known as methanediol or methylene glycol.⁸⁴ However, the equilibrium that exists between methylene glycol and formaldehyde gas compounds in solution can be readily shifted.⁸⁵ Thus, products that contain such solution will inevitably emit formaldehyde gas where it can be inhaled, particularly when subjected to heat, for example with a flatiron.⁸⁶ That is why EPA considers methylene glycol a “synonym” of formaldehyde.⁸⁷ That also is why OSHA’s formaldehyde regulations cover formaldehyde gas, as well as “solutions, and materials that release formaldehyde.”⁸⁸ Even industry groups such as the American Chemistry Council acknowledge that the “scientific community widely considers methylene glycol [to be] ‘formaldehyde in solution.’”⁸⁹ Of course that has not stopped makers of keratin hair-straighteners from arguing that methylene glycol is wholly different from

⁷⁹ Infra III.2.A.

⁸⁰ See infra III.1.B.xi (assessing Cadiveu’s unconventional test results which vastly undercount the amount of formaldehyde used in its formula).

⁸¹ Supra III.1.A.i.

⁸² IARC, Formaldehyde, supra note 12, at 40.

⁸³ Or. OSHA Report, supra note 18, at 12.

⁸⁴ Id. at 12-13.

⁸⁵ Id. at 13.

⁸⁶ Id. (“Solutions of formaldehyde left in the open air release gaseous formaldehyde” and at a faster rate when heated.).

⁸⁷ EPA, Formaldehyde (CASRN 50-00-0), <http://www.epa.gov/iris/subst/0419.htm> (last visited Mar. 9, 2011).

⁸⁸ 29 C.F.R. § 1910.1048(a).

⁸⁹ Press Release, Am. Chem. Council, Position Statement of the American Chemistry Council’s Formaldehyde Panel on the Formaldehyde Content of Certain Hair-Care Products (Dec. 9, 2010), <http://www.americanchemistry.com/11550> [hereafter Am. Chem. Council, Position] (“the formaldehyde content, (ie., both gaseous and in solution), should be taken into account when characterizing formaldehyde exposures and protecting workers and consumers”).

formaldehyde gas based on the fact that they have different Chemical Abstract Services (CAS) registry numbers.⁹⁰ Yet such designations do not account for whether compounds exist in solution in chemical equilibrium, as is the case with methylene glycol and formaldehyde.⁹¹ Nor do they reflect the fact that methylene glycol is conventionally treated as a synonym of formaldehyde. Thus, companies may continue to make a “rigid distinction between gaseous . . . and hydrated formaldehyde,”⁹² but that hardly excuses the claims and omissions identified herein, especially when the risks associated with the two are virtually identical.⁹³

The following accounts for some of the claims and omissions used by companies to conceal whether their products expose users to excessive levels of formaldehyde.

i. R&L Trading Corp.’s Soft-Liss Professional Line Products

R&L Trading Corp. (R&L)⁹⁴ makes a number of claims regarding the formaldehyde content of its Soft-Liss Professional Line products. For one, the company conspicuously states on its welcome page, “None of our products contain any formaldehyde. They are all formaldehyde FREE.”⁹⁵ The claim also appears at the top of each individual product page for its various kits.⁹⁶ Additionally, R&L claims that its Strawberry Kit will make it “impossible for anyone to resist the fantastic sweet aroma that your hair will exhale.”⁹⁷

Fact. The Irish Medical Board found that the company’s products “contain high levels of formaldehyde” in “excess of the permitted level of 0.2% when used as a preservative.”⁹⁸

⁹⁰ E.g., Complaint, *GIB, LLC v. Or. OSHA*, No. 1012-17526 (Or. Cir. Ct. filed Dec. 15, 2010).

⁹¹ See CIR, *Formaldehyde and Methylene Glycol*, *supra* note 20, at 4 (“[E]quilibrium between methylene glycol and formaldehyde strongly favors methylene glycol, at room temperature[,] . . . [but, a] formulation that is of a higher density and/or is subjected to higher temperatures is likely to shift favoritism towards non-hydrated formaldehyde.”) Note that methylene glycol does not exist “outside of an aqueous solution.” *Id.*

⁹² Or. OSHA Report, *supra* note 18, at 12.

⁹³ *Id.* at 2.

⁹⁴ R&L is headquartered in Miami, Fla. See *Soft-Liss Professional Line, Contact Us*, <http://www.softliss.com/ingles/contacto.html> (last visited Mar. 11, 2011). Additional company information is available through the Florida Department of State Division of Corporations and the U.S. Patent and Trademark Office. R&L’s employer identification number is 208522171 and its trademark registration number for “Soft-Liss” is 3590672.

⁹⁵ Ex. B at 1.

⁹⁶ *Id.* at 1-2.

⁹⁷ *Id.* at 1.

⁹⁸ Press Release, Irish Meds. Bd., *Concerns Relating to Use of Certain Hair Straightening Products – Update* (Nov. 29, 2010) (copy included in Ex. C at 3) [hereafter Irish Meds. Bd., *Concerns*].

ii. KeraGreen Keratin and Protein Hair System by LBD

KeraGreen by LBD⁹⁹ prominently claims on its welcome page that its product is “non toxic, formaldehyde free, [and] rich with organic and natural ingredients.”¹⁰⁰ KeraGreen touts these purported features to set its product apart “from all other keratin hair treatments in the market”¹⁰¹ When individuals visit the KeraGreen welcome page they also see a banner at the top of their browser window that reinforces those claims by stating, “KeraGreen Organic Keratin, Formaldehyde Free”¹⁰²

Fact. Oregon OSHA tested 2 samples of KeraGreen’s Keratin and Protein Hair Treatment and found them to contain between 1.4 and 1.6 percent formaldehyde.¹⁰³

iii. Tahe Thermo Keratin Hair Treatment

Tahe Cosmetics Professional Products, LLC (Tahe)¹⁰⁴ describes its Thermo Keratin Treatment as “Formol free” in its online product information.¹⁰⁵

Fact. The Irish Medical Board issued an alert to inform consumers that Tahe’s products “contain high levels of formaldehyde” in “excess of the permitted level of 0.2% when used as a preservative.”¹⁰⁶

iv. Brazilian Gloss Brazilian Keratin Treatment

Brazilian Gloss¹⁰⁷ states on its welcome page that its product is comprised of a “gentle, pure, no harsh chemical formula,”¹⁰⁸ suggesting to stylists and consumers that they will not be exposed to formaldehyde and related health effects when using the product.

⁹⁹ KeraGreen by LBD is owned by DME Global Enterprises, Inc. (DME) which is headquartered in Miami, Fla. DME has registered the “KeraGreen by LBD” mark with the U.S. Patent and Trademark Office (Registration No. 3872634). Additionally, the Florida Department of State Division of Corporations has assigned DME’s articles of incorporation with document number P10000018217.

¹⁰⁰ Ex. B at 3.

¹⁰¹ Id.

¹⁰² Id.

¹⁰³ Or. OSHA Report, supra note 18, at 22.

¹⁰⁴ Tahe lists a business address in Roswell, Ga. The Georgia Secretary of State Corporations Division has assigned the company control number 08086686.

¹⁰⁵ Ex. B at 4.

¹⁰⁶ Irish Meds. Bd., Concerns, supra note 98 (copy included in Ex. C at 3).

¹⁰⁷ Brazilian Gloss, LLC, lists its principal place of business in Newport Beach, Cal. The California Secretary of State lists the company’s entity number as 201029910112. However, the company appears to be incorporated in Delaware (File Number 4784102). It also has registered the “Brazilian Gloss” mark with the U.S. Patent and Trademark Office (Serial Number 77970092).

¹⁰⁸ Ex. B at 6.

Fact. Oregon OSHA tested a sample of Brazilian Gloss Keratin Smoothing Gloss and found it to contain 7.3 percent formaldehyde.¹⁰⁹

v. Keratin Express Formula

On November 18, 2010, Keratin Express¹¹⁰ issued a press release on its website regarding its formula and formaldehyde as an ingredient.¹¹¹ In the press release, Keratin Express downplays the risks associated with formaldehyde by underscoring the fact that formaldehyde “occurs as a natural product in most living systems” and that individuals “breathe it every day both indoors and out.”¹¹² Keratin Express further claims that the “current Keratin Express formula contains no known formaldehyde, nor does it contain methylene glycol, formalin, or any other known form of formaldehyde in solution.”¹¹³ At the end of its press release Keratin Express states again in underlined text that “Formaldehyde is not part of [its] ingredients or formula and is not necessary for the performance of the product.”¹¹⁴

Fact. Oregon OSHA found hazardous levels of formaldehyde in 7 test samples ranging from 1.0 to 1.2 percent.¹¹⁵

vi. Marcia Teixeira Brazilian Keratin Treatment

On its company page Marcia Teixeira¹¹⁶ claims that its formula “does not involve a harsh, chemical treatment process” and “can be used safely.”¹¹⁷ Elsewhere on Marcia Teixeira’s site the company responds to various reports concerning the detection of formaldehyde in its products.¹¹⁸ Here Marcia Teixeira states that it “cannot, and ha[s] never claimed that [its products] are formaldehyde free.”¹¹⁹ However, the company maintains that “formaldehyde is not an ingredient in [its] treatments,” despite acknowledging that it uses “Methylene glycol.”¹²⁰ Accordingly, Marcia Teixeira’s distinction between formaldehyde and methylene glycol, combined with its claims about safety, conceal whether individuals will be exposed to formaldehyde when using the company’s products.

¹⁰⁹ Or. OSHA Report, *supra* note 18, at 22.

¹¹⁰ Keratin Express, LLC, is headquartered in Miami, Fla. The Florida Secretary of State Corporations Division lists its document number as L10000063228.

¹¹¹ Ex. B at 7.

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ Or. OSHA Report, *supra* note 18, at 22.

¹¹⁶ Marcia Teixeira is manufactured by M&M International, Inc., which is headquartered in Delray Beach, Fla. The Florida Secretary of State Corporations Division lists the company’s document number as P06000020343 and its employer identification number as 204329293.

¹¹⁷ Ex. B at 8.

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ *Id.*

Fact. Health Canada detected 1.7 percent formaldehyde in its Advanced Brazilian Keratin Treatment and 1.6 percent in its Chocolate De-Frizzing Treatment.¹²¹ Oregon OSHA tested 4 more samples of Marcia Teixeira's Brazilian Keratin Treatment and found between 1.2 and 2.0 percent formaldehyde.¹²² Finally, the French Health Products Safety Agency issued a recall for the company's Chocolate Extreme De-Frizzing Treatment product because it found formaldehyde above safe levels.¹²³

vii. IBS Beauty's i-Straight System

IBS Beauty, Inc. (IBS)¹²⁴ claims on its website that its i-Straight hair-straightener is "The safest . . . system for straightening" hair.¹²⁵ It also claims that the i-Straight System "will safely straighten almost anyone's hair."¹²⁶ However, nowhere on its website does the company mention that stylists and consumers may be exposed to formaldehyde as a consequence of using the product.¹²⁷ Also note that IBS claims that its i-Refresh System produces smooth-hair results "without the . . . worries of formaldehyde,"¹²⁸ which implies that one might have grounds to worry about the i-Straight System's formaldehyde content.

Fact. Health Canada tests revealed that the company's i-Straight Advanced Keratin Treatment contains formaldehyde levels of 2.3 percent.¹²⁹

viii. Coppola Keratin Keratin Complex Smoothing Therapy

In a press release published on October 15, 2010, Coppola¹³⁰ states that its formula contains "Timonacic acid, a benign antioxidant . . . which is part of an aldehyde group that . . . acts as an organic preservative."¹³¹ Coppola highlights this ingredient to distinguish it from other hair-

¹²¹ Press Release, Health Can., Several Professional Hair Smoothing Solutions Contain Formaldehyde, (Dec. 10, 2010), http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2010/2010_222-eng.php [hereafter Health Can., Several Professional Solutions].

¹²² Or. OSHA Report, *supra* note 18, at 22.

¹²³ French Health Products Safety Agency (AFSSAPS), Liste des Produits de Lissage Capillaire Contenant des Concentrations en Formaldéhyde Supérieures à la Limite Réglementaire et Identifiés en France 1 (2010), http://www.afssaps.fr/var/afssaps_site/storage/original/application/09bc0ee18beaa21d41ea244006388b7e.pdf [hereafter AFSSAPS].

¹²⁴ IBS is headquartered in Santa Fe Springs, Cal. The California Secretary of State has assigned IBS entity number C2386195.

¹²⁵ Ex. B at 9.

¹²⁶ *Id.*

¹²⁷ *Id.*; see also IBS Home Page, <http://www.ibsbeauty.com/index.shtml> (last visited Mar. 13, 2011).

¹²⁸ Ex. B at 9.

¹²⁹ Health Can., Several Professional Solutions, *supra* note 121.

¹³⁰ According to its website, Coppola's corporate headquarters are located in Boca Raton, Fla. Coppola Keratin Complex Smoothing Therapy, Contact Us, <http://www.keratincomplex.com/contact.htm> (last visited Mar. 14, 2011).

¹³¹ Ex. B at 10.

straighteners that contain “free formaldehyde.”¹³² According to Coppola, the difference between formulas containing free formaldehyde “and Keratin Complex’s bonded aldehydes is that the latter is not harmful.”¹³³ However, these statements are misleading because they hide the fact that a formula does not have to contain raw formaldehyde to release the gas when exposed to air and/or heat.¹³⁴

Fact. Health Canada found that Coppola’s Keratin Complex Smoothing Therapy contained 1.8 percent formaldehyde.¹³⁵ Likewise, Oregon OSHA tested 3 samples of the product and found formaldehyde levels between 1.7 and 2.3 percent.¹³⁶ The Australian Competition and Consumer Commission reported finding elevated levels of formaldehyde, as well.¹³⁷ Lastly, the French Health Products Safety Agency recalled Coppola’s Keratin Complex products in light of their excessive formaldehyde levels.¹³⁸

ix. Silkening Technologies Pro Collagen Rx Keratin Treatment

The U.S. website for Silkening Technologies¹³⁹ makes no mention of the ingredients used in its Pro Collagen Rx Keratin Treatment and materially omits information about the risk of formaldehyde exposure as a consequence of using the product.¹⁴⁰ Moreover, the “Silkening Technologies Canada” site,¹⁴¹ which appears to be operated by distributor of the product, states that the Pro Collagen Rx Keratin Treatment is “Specifically blended to be safe” with “no bad aromas.”¹⁴² It also claims that it is “formulated to be . . . safer than any other product.”¹⁴³

¹³² Id.

¹³³ Id.

¹³⁴ E.g., Trichovedic, Keratin Smoothing Treatment Formaldehyde Test Results, <http://www.trichovedic.com.au/news/keratin-smoothing-treatment-formaldehyde-test-results/> (last visited Mar. 18, 2011).

¹³⁵ Health Can., Several Professional Solutions, supra note 121.

¹³⁶ Or. OSHA Report, supra note 18, at 22.

¹³⁷ Press Release, Austl. Competition & Consumer Comm’n, Dateline Imports Pty Ltd – Keratin Complex Smoothing Therapy, Smoothing Therapy for Blonde Hair & Express Blow Out (Oct. 28, 2011), <http://www.recalls.gov.au/content/index.phtml/itemId/996798> (“Tests show that the products contain ‘free’ formaldehyde in excess of the level considered safe.”).

¹³⁸ AFSSAPS, supra note 123, at 1.

¹³⁹ Silkening Technologies appears to be headquartered in Boca Raton, Fla. According to the U.S. Patent and Trademark Office, Silkening Technologies, LLC, registered the mark “Silkening Technologies” on Nov. 18, 2009 (Registration Number 3930224). The Florida Department of State Corporations Division also has record entries for Silkening Technologies, Inc. (Document Number P10000007580) and Silkening Technologies, LLC (Employer Identification Number 943487044) that both list the same contact information as their principal business address.

¹⁴⁰ See Silkening Technologies, Pro Collagen Rx Keratin Treatment by Biage, http://keratintreatmentbybiage.com/SILKENING_TECHNOLOGIES/Welcome.html (last visited Mar. 13, 2011).

¹⁴¹ Silkening Technologies, Pro Collagen Rx Keratin Treatment, <http://silkeningtechnologies.ca/> (last visited Mar. 13, 2011).

¹⁴² Ex. B at 5.

¹⁴³ Id.

Finally, the site mentions the fact that it emits “No unpleasant fumes or odour” as one of product’s main benefits.¹⁴⁴

Fact. Health Canada detected formaldehyde levels of 2.8 percent in Silkening Technologies’ Pro-Collagen RX Keratin Treatment.¹⁴⁵

x. **Brazilian Blowout Açai Professional Smoothing (“Original”) Solution**

Brazilian Blowout¹⁴⁶ initially labeled its original solution bottle as “formaldehyde free” and made a similar claim on the company’s website where it described the product’s key features.¹⁴⁷ Brazilian Blowout removed those statements in February 2011, but continues to omit material information regarding formaldehyde exposure as a consequence of use.¹⁴⁸

Fact. When EWG called Brazilian Blowout on February 24, 2011, a company representative admitted that the original solution releases “micro-fractions” of formaldehyde during the treatment process.¹⁴⁹ EWG could not find an accepted definition for the term “micro-fraction.” However, FDA should note that the Oregon OSHA found hazardous levels of formaldehyde in 37 test samples of the product ranging from 6.8 to 11.8 percent.¹⁵⁰ Despite Brazilian Blowout’s criticism of the report,¹⁵¹ Oregon OSHA reiterated on February 10, 2011, that it had “not changed its position” regarding the findings.¹⁵² Furthermore, Health Canada and the Irish Medical Board also detected high levels of formaldehyde in Brazilian Blowout, which only reinforces Oregon OSHA’s findings.¹⁵³

¹⁴⁴ Id.

¹⁴⁵ Health Can., Several Professional Solutions, supra note 121.

¹⁴⁶ GIB, LLC, d/b/a “Brazilian Blowout” lists its business address as 6855 Tujunga Ave., North Hollywood, CA 91605.

¹⁴⁷ Ex. B at 11.

¹⁴⁸ Id. at 12.

¹⁴⁹ On Feb. 24, 2011, EWG called Brazilian Blowout at (877) 779-7706 and spoke with a representative who said her name was “Michelle.” When EWG inquired about changes made to the original solution’s bottle and product information, the representative admitted that Brazilian Blowout had had “a labeling issue” because the product releases a “micro-fraction” of formaldehyde. However, the representative added that the company does not put formaldehyde “in the product, itself.”

¹⁵⁰ Or. OSHA Report, supra note 18, at 22.

¹⁵¹ Brazilian Blowout filed a legal complaint against Oregon OSHA in December 2010, claiming that the agency used misleading test methods that overstate formaldehyde levels found in various hair-straighteners, including Brazilian Blowout. Complaint, GIB, LLC v. Or. OSHA, No. 1012-17526 (Or. Cir. Ct. filed Dec. 15, 2010). According to Brazilian Blowout, Oregon OSHA improperly equated methylene glycol with formaldehyde gas when calculating products’ formaldehyde content. Id. However, note that Brazilian Blowout dropped its lawsuit against Oregon OSHA less than three months after filing. Katy Muldoon, Brazilian Blowout Drops Lawsuit Against Oregon OSHA and OHSU, Oregonian, Mar. 2, 2011, http://www.oregonlive.com/health/index.ssf/2011/03/brazilian_blowout_drops_lawsui.html.

¹⁵² Press Release, Or. OSHA, Statement on Hair Smoothing Products (Feb. 10, 2011), http://www.oshareg.org/admin/newsrelease/2011/nr2011_02.pdf.

¹⁵³ Health Can., Brazilian Blowout, supra note 77; Irish Meds. Bd., Recall, supra note 78 (copy in Ex. C at 1).

xi. Cadiveu Brazilian Keratin Smoothing Formula

Cadiveu's¹⁵⁴ website provides a company response to the detection of formaldehyde in various keratin hair-straighteners.¹⁵⁵ In its statement Cadiveu claims that its formula "does not contain formaldehyde as a functional ingredient in the hair smoothing process" according to independent lab results.¹⁵⁶ Cadiveu also tries to ease public concerns about its formula by stressing the fact that "Traces of formaldehyde are found naturally" and that "Fortunately, at these trace levels, formaldehyde is considered safe."¹⁵⁷ Of course, this latter point is irrelevant because it has nothing to do with the actual composition of Cadiveu's product.

Fact. The lab tests cited by Cadiveu utilized "quantitative 13C nuclear magnetic resonance" (NMR).¹⁵⁸ This methodology allows one to differentiate between formaldehyde in gas and formaldehyde hydrated in water in the form of methylene glycol.¹⁵⁹ However, the separation of formaldehyde forms is not only irrelevant from a human health perspective, but also is at odds with industry's view on testing for the chemical.¹⁶⁰ For example, the American Chemistry Council Formaldehyde Panel maintains the position that "both formaldehyde gas and formaldehyde reacted in water determine the formaldehyde content of a product."¹⁶¹ Despite Cadiveu's claims and analytical methods, Health Canada tested the company's Brazilian Thermal Reconstruction product and found formaldehyde levels of 7.0 percent.¹⁶²

xii. GKHair ("Global Keratin") Treatment

GKHair¹⁶³ recently issued a statement to French consumers to inform them about its new "Light Tame" formula.¹⁶⁴ The company created the product after health officials reported detecting high levels of formaldehyde in various hair-straighteners.¹⁶⁵ According to GKHair, "the company has been in full compliance with all regulations worldwide and [has] never made any

¹⁵⁴ According to Cadiveu's website, the company is headquartered in Sao Paulo, Braz. Cadiveu Professional, Contact Us, http://www.cadiveu.com/uk/fale_conosco.html (last visited Mar. 13, 2011).

¹⁵⁵ Ex. B at 13.

¹⁵⁶ Id.

¹⁵⁷ Id.

¹⁵⁸ Id. at 14.

¹⁵⁹ See T.W. Graham Solomons, Organic Chemistry 573 (6th ed. 1996) ("Each type of carbon atom in an ordinary organic molecule produces only one 13C NMR peak.").

¹⁶⁰ Am. Chem. Council, Position, supra note 89, at 2.

¹⁶¹ Id.

¹⁶² Health Can., Several Professional Solutions, supra note 121.

¹⁶³ GKHair, formerly "Global Keratin," appears to have a company address in Ft. Lauderdale, Fla. According to the U.S. Patent and Trademark Office, the "GK Hair" mark is registered by GK World Holding, LLC (International Registration Number 1050324). Additionally, the Florida Secretary of State Corporations Division has assigned GK World Holding, LLC, document number L10000000714.

¹⁶⁴ Ex. B at 15.

¹⁶⁵ Id.

false claims” about its products.¹⁶⁶ Yet the company goes on to state that government officials are mistakenly “confusing . . . Formaldehyde . . . with Methylene Glycol,”¹⁶⁷ suggesting that its original Taming System formula contains the latter. If that is the case, then GKHair is withholding material information about formaldehyde exposure as a consequence of using the original formula. Of course, FDA should note that GKHair still markets its original formula in the United States where it has not made available the Light Tame alternative.¹⁶⁸

Fact. Health Canada tests for Global Keratin show that its Strawberry Taming System contains 3.0 percent formaldehyde, its Strawberry Resistant Taming System contains 4.4 percent formaldehyde, and its Strawberry Light Wave Taming System with Juvexin contains 1.4 percent formaldehyde.¹⁶⁹ Australia’s Competition and Consumer Commission also reported finding excessive levels of formaldehyde in Global Keratin’s Hair Taming System products.¹⁷⁰

xiii. QOD Brazilian Keratin Formula

QOD¹⁷¹ acknowledges on its website that “Formaldehyde Free” keratin hair-straighteners are nothing more than a “marketing gimmick” and a “Myth.”¹⁷² However, QOD’s “notes on formaldehyde” suggest that the company’s formula is safer to use than its competitors’ products because it does not contain “industrially manufactured raw formaldehyde.”¹⁷³ QOD acknowledges that keratin hair-straighteners producing results “lasting more than several weeks [are] [] potent salon products,” but materially omits information about exposure to significant levels of formaldehyde as a consequence of using its treatment.¹⁷⁴

¹⁶⁶ Id.

¹⁶⁷ See id.

¹⁶⁸ See id. (The fact that GKHair’s new Light Tame formula is “only available in Europe, Canada and Australia” indicates that the company still sells its original line in the United States.).

¹⁶⁹ Health Can., Several Professional Solutions, supra note 121.

¹⁷⁰ Press Release, Austl. Competition & Consumer Comm’n, Clemnor Pty Ltd - Global Keratin Hair Taming System with Juvexin LIGHT WAVE 300mL & 1000mL and Global Keratin Hair Taming System with Juvexin CURLY 300mL & 1000mL (Jan. 18, 2011), <http://www.recalls.gov.au/content/index.phtml/itemId/999134> (“products contain a concentration of ‘free’ formaldehyde in excess of the allowable limit as stipulated in the Standard for the Uniform Scheduling of Medicines and Poisons”).

¹⁷¹ According to QOD’s website, the company is headquartered in Porto Alegre, Braz. QOD Authentic Brazilian Keratin, About QOD, <http://www.qodusa.com/about-qod-usa.shtml> (last visited Mar. 14, 2011). However, the U.S. Patent and Trademark Office indicates that the “QOD” mark (Serial Number 77884885) for hair products is registered to Nicholas Johnson, who lists an address at 166 Geary St., Ste. 1305, San Francisco, CA 94108. Mr. Johnson’s LinkedIn Profile lists one of his job titles as “CEO, QOD USA.” See LinkedIn Profile of Nick Johnson, <http://www.linkedin.com/pub/nick-johnson/9/6a6/b93> (last visited Mar. 13, 2011).

¹⁷² Ex B at 16.

¹⁷³ Id.

¹⁷⁴ Id.

Fact. Oregon OSHA tested a sample of QOD Gold Solution and found formaldehyde levels of 2.0 percent.¹⁷⁵

In light of these claims and omissions, and the health hazard posed by formaldehyde, EWG requests that FDA investigate the companies identified above and take steps to prevent them from deceiving the public about their products' safety. EWG also asks FDA to promulgate regulations that require warning labels for hair-straighteners containing formaldehyde, including formaldehyde in solution, as well as other formaldehyde-releasing ingredients. Lastly, EWG asks FDA to review whether a ban on such ingredients might be a more effective measure to protect public health.

2. Legal Grounds

The FDCA gives FDA ample authority to take the requested actions, largely based on its adulterated and misbranded cosmetic provisions which apply to hair-straighteners.

A. Grounds to Address Deceptive Claims By Identified Keratin Hair-Straightener Companies

Section 301 of the FDCA prohibits the introduction or delivery of misbranded cosmetics into interstate commerce. 21 U.S.C. § 331(a). A cosmetic is misbranded if its "labeling is false or misleading in any particular." 21 U.S.C. § 362(a). To decide whether cosmetic labeling is false or misleading, FDA takes into account both the representations made or suggested about the product, as well as omissions of material fact regarding consequences that may result from using it under ordinary conditions.¹⁷⁶ 21 U.S.C. § 321(n); 21 C.F.R. § 1.21.

Should FDA accept health agencies' findings with regard to formaldehyde and certain hair-straighteners then each one of the companies identified in this petition is either: (1) making express or misleading claims about their products' formaldehyde content, suggesting that little to none exists when tests show quite the opposite; or (2) omitting material information about exposure to formaldehyde as a consequence of using them. Such information is clearly material in light of the substantial health risks associated with the chemical,¹⁷⁷ particularly when inhaled, as is the case here.

¹⁷⁵ Or. OSHA Report, *supra* note 18, at 22.

¹⁷⁶ FDA, *Cosmetic Labeling Guide* (1991),

<http://www.fda.gov/Cosmetics/CosmeticLabelingLabelClaims/CosmeticLabelingManual/ucm126444.htm>.

¹⁷⁷ *C.f.* Letter from Twyla Thompson, Regulatory Review Officer, FDA Division of Drug Marketing, Advertising, and Communications, to Laura A. Navalta, Senior Vice President, Clinical and Regulatory, Novalar Pharmaceuticals, Inc. (Jan. 22, 2010),

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM199746.pdf> (warning letter to drug company states that "[p]romotional materials are misleading if they fail to reveal material facts . . . [such as] present[ing] information about risks associated with a drug . . ."). For comparative purposes, note that the U.S.

Claims highlighted in this petition largely come from the websites of companies that sell these products. Yet based on additional EWG research, labeling for these products still appears to omit risk information about formaldehyde exposure, thus perpetuating the companies' deceptive marketing. Regardless of where these claims appear, however, FDA should take into account the fact that the U.S. Federal Trade Commission (FTC) is relying on it to take the lead on this matter on behalf of the public.¹⁷⁸

Once FDA determines that a cosmetic is misbranded, FDA has a range of options on how to respond, including, but not limited to: (i) collecting and assessing test samples of cosmetics to address safety concerns about ingredients, pursuant to 21 U.S.C. § 374; (ii) requesting that companies initiate a voluntary recall of their misbranded cosmetics, pursuant to 21 C.F.R. § 7.40(b); and (iii) issuing warning letters to manufacturers of misbranded cosmetics, pursuant to 21 U.S.C. § 336. FDA also can pursue non-enforcement measures such as further publicizing deceptions like the ones identified above, pursuant to 21 U.S.C. § 375(b), or by taking any other action deemed necessary to ensure the efficient enforcement of the FDCA, pursuant to 21 U.S.C. § 371(a). Given the number of companies using deception to hide their products' formaldehyde content, as well as the health concerns implicated by those acts, FDA should do everything it can to give this matter the attention it deserves.

B. Grounds to Require Formaldehyde Warning Label

FDA has authority to require specific warning labels for cosmetics. 21 U.S.C. §§ 321(n), 362(a), 371(a) and 21 C.F.R. § 740.1(b). FDA has taken such action when necessary to address health hazards unique to a particular type of cosmetic.¹⁷⁹ For example, FDA requires a warning label for cosmetics sold in self-pressurized containers to indicate that they can explode when “puncture[d] or incinerate[d].” 21 C.F.R. § 740.11. FDA imposes a similar requirement for foaming bath detergents to warn consumers that “prolonged exposure may cause irritation to the skin and urinary tract.” 21 C.F.R. § 740.17. Along the same line, hair-straighteners that contain formaldehyde and/or formaldehyde-releasing chemicals present a unique health hazard of their own. After all, such products invariably release formaldehyde during the treatment process, subjecting anyone located nearby to the risks identified above. Accordingly, so long as these ingredients are found in hair-straighteners, FDA can and should require a warning label to highlight the health concerns associated with formaldehyde exposure.

Federal Trade Commission (FTC) considers claims/omissions involving safety to be presumptively material. FTC, Policy Statement on Deception § IV, appended to Cliffdale Associates, Inc., 103 FTC 110, 174 (1984).

¹⁷⁸ See Ex. D at 4, 5 (contains copies of records obtained from FTC in response an EWG FOIA request).

¹⁷⁹ FDA's authority to require that cosmetics carry specific warning labels was affirmed in Cosmetic, Toiletry, and Fragrance Association, Inc., v. Schmidt, 409 F. Supp. 57 (D.D.C. 1976) (“regulations were properly promulgated under [FDA's] authority pursuant to 21 U.S.C. § 371(a).”). FDA considers misbranded any cosmetic that fails to carry a required warning label. 21 U.S.C. §§ 321(n), 362(a), and 21 C.F.R. § 1.21.

C. Grounds to Ban Formaldehyde and Formaldehyde-Releasing Chemicals from Hair Straighteners Should FDA Review Find Need for Such Action

Section 301 of the FDCA prohibits the introduction and delivery of adulterated cosmetics into interstate commerce. 21 U.S.C. § 331(a). The FDCA classifies cosmetics as “adulterated” if they contain any substance that “may render it injurious to users under . . . conditions of [customary] use.” 21 U.S.C. § 361(a). At times, FDA has used this provision, along with the Commissioner’s general authority under 21 U.S.C. § 371(a), to ban or restrict the use of cosmetic ingredients shown to meet that threshold. For example, FDA banned the use of methylene chloride as a cosmetic ingredient when it had “sufficient” evidence to conclude that the chemical is an animal carcinogen.¹⁸⁰ FDA also banned zirconium from aerosol cosmetics when toxicology data indicated that the substance might generate “human skin granulomas as well as toxic effects in the lungs and other internal organs of test animals.”¹⁸¹ Likewise, FDA barred vinyl chloride from aerosol cosmetics when “sufficient scientific data” showed that the compound “can result in acute toxicity [such as dizziness and headache when] . . . inhaled at high concentrations,” as well as “carcinogenic effects in animals as a result of inhalation exposure.”¹⁸² Numerous studies show that formaldehyde can generate a range of adverse health effects including cancer.¹⁸³ Thus, were FDA to review the risks associated with formaldehyde exposure it would find compelling evidence to justify a similar rulemaking, at least with regard to cosmetics that readily emit fumes such as hair-straighteners.

IV. CONCLUSION

For the aforesaid reasons, the undersigned hereby petitions the Commissioner to take the actions requested above to ensure that consumers are adequately protected from the potential adverse health effects posed by hair-straighteners that contain formaldehyde, including formaldehyde in solution, and/or formaldehyde-releasing ingredients.

V. ENVIRONMENTAL IMPACT

The actions requested in this petition do not require the preparation of an environmental assessment because they are subject to categorical exclusions set forth in 21 C.F.R. § 25.30.

¹⁸⁰ Ban on the Use of Methylene Chloride as an Ingredient of Cosmetic Products, 54 Fed. Reg. 27,328, 27,338 (June 29, 1989) (codified at 21 C.F.R. § 700.19).

¹⁸¹ Aerosol Drug and Cosmetic Products Containing Zirconium, 42 Fed. Reg. 41,374, 41,376 (Aug. 16, 1977) (codified at 21 C.F.R. § 700.16).

¹⁸² Vinyl Chloride as an Ingredient and Cosmetic Aerosol Products, 39 Fed. Reg. 30,830 (Aug. 26, 1974) (codified at 21 C.F.R. § 700.14).

¹⁸³ Supra III.1.A.ii.

VI. ECONOMIC IMPACT

No economic impact statement is required for the requested action because FDA has not requested one. 21 C.F.R. § 10.30(b).


VII. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully Submitted,



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