

**Hair Smoothing Product Labeling Study
Moderator's Guide for Salon Stylists
September 2016**

Objective

The FDA Hair Smoothing Product Labeling Study is designed to help FDA better understand how salon stylists, salon clients and retail consumers of permanent hair smoothing products understand current and draft cautionary labels, developed by FDA, that appear on professional hair smoothing products that release formaldehyde. The findings from the research will provide background information to the FDA's Office of Cosmetics and Colors on certain professional hair smoothing products that may be hazardous when used improperly.

Specifically, this focus group research is to examine participant's reactions to proposed cautionary statements on professional hair-smoothing products that release formaldehyde. FDA notes that well-designed warning labels can be very effective in catching the attention of consumers and communicating precautions to be taken while using these products. Unless the message is clear and easily understood, the warning is likely to be ineffective. Critical design elements include: font size, color, spacing, and location of warning message on the product. Pictorial images/symbols may also be critical in the warning statements in order to address users for whom English is a second language (while these focus groups will include participants with varied racial and ethnic backgrounds, English literacy will be a screening criterion). The purpose is to examine whether the FDA-proposed warning messages sufficiently inform consumers and salon workers about the potential health risks associated with formaldehyde-releasing cosmetics and provides adequate direction for safe use.

I. Introduction [3 minutes]

Thanks for joining us today. I'm _____, and I'm from Westat, a private research company based in Rockville, MD. My colleague, _____, is from the U.S. Food and Drug Administration (FDA). On behalf of FDA, Westat is conducting discussions with hair stylists at hair shows. The purpose of our discussion today is to hear your views and opinions on the use of different types of hair products and how you communicate information about these hair products to your clients. We will also look at different labeling options on hair smoothing products. Your insights are very important to us and your time today is appreciated. We will have about 90 minutes for our discussion.

[Moderator: Hand out consent forms as participants arrive. The consent form will be summarized by the moderator during introduction to ensure that all of the required consent points are covered. Any questions about the consent form will be answered at this point.]

Before we get started there are a few things I should mention to comply with the protocol for this study. We have provided a consent form for you all to sign. Please make sure you have read through the form. We would like to audio and video record this discussion. The audio recordings will be transcribed so that we don't miss the important things that you say. The recordings, transcripts, and any notes we have will be stored on Westat's and FDA's secure servers and will be destroyed after the project is complete. Your contribution to our discussion will be anonymous and your names, the names of your salons or any other personally identifying information will not appear in any report that we write. Your participation in this discussion is voluntary and you may stop participating at any time.

Do you have any questions? [ANSWER ALL QUESTIONS]

If you are ready to proceed I will start the recordings and turn on the video camera.

Please sign the consent form; my colleague XXX will collect the forms.

II. Ground Rules [2 minutes]

Before we begin, I want to review a few ground rules for our discussion.

1. There are no right or wrong answers in today's discussion. We want to know your honest opinions and experiences.
2. Everyone's participation is important; we want to hear from everybody.
3. It is OK to disagree.
4. Please speak up (speak loudly).
5. Please speak one at the time so we can hear all the responses.
6. Please turn off your cell phones or anything else that may make it difficult to concentrate.
7. If at any point you feel uncomfortable with my questions, simply let me know that you prefer not to answer.
8. Do you have any questions before we begin?

III. Introductions of Participants [5 minutes]

I'm here to facilitate and guide our discussion but I mainly want to hear from you, about your experiences and opinions. [Moderator: have participants' introduction questions written up on a flip chart.]

1. Let's begin with introducing ourselves; please tell me:
 - your first name,
 - which city or county, and state your salon is in,
 - how many stations are in your salon,
 - your role or roles at the salon (owner, manager, stylist, colorist, etc.),
 - how long you have been working as a hair stylist,
 - what hair smoothing/straightening treatments you do; if none, are you hoping to do it in the future?

[Moderator: the terms: "hair smoothing" and "hair straightening" will be used interchangeably unless established during the discussion that they mean different things.]

IV. Warm-up [5 minutes]

I would like to talk briefly about what motivated you to attend the show. [Probe for: learning new procedures, new products, etc.]

V. Hair Smoothing/Straightening Practices and Habits [25 minutes]

Many of you mentioned during your qualifying interview that hair smoothing is one of the services you offer; I would like to talk a bit about that.

1. What types of hair smoothing/straightening do you do? [Probe for: Brazilian blowout, keratin treatment, relaxer, other?] Are there any differences between the terms “hair smoothing” and “hair straightening”?
2. Now, I would like us to concentrate on hair smoothing procedures that are generally called Brazilian blowout or keratin treatments. How often do you do Brazilian blowouts/keratin treatments? Are you the only one in your salon who does it? If yes, why is that the case?
3. What are your clients' reasons for having the Brazilian blowout or keratin treatment done to their hair? [Probe for: lasting effects, smooth hair, etc.]
4. What type of products do you use for these hair smoothing procedures? What are some of the names of the products you use? [Moderator: please write down responses on a flip chart.]
5. Do you provide any consultation to your clients at the time of making an appointment, or when they are considering hair smoothing? If yes, what is the content of that consultation?
6. What information, if any, do you provide to your client at the beginning of your hair smoothing appointment? What about during and after the procedure?
7. What information, if any, about the smoothing product itself do you provide to your clients? Is it any different for clients having the hair smoothing procedure done for the first time? Are there any specific questions asked by your clients? Do they have any concerns? What are they? If they have no questions, why do you think that is the case?
8. [If this did not come up in the discussion so far, ask:] Do you know the ingredients in the hair smoothing or straightening products you use? Do any of these ingredients make you concerned?
9. Do products that you use contain formaldehyde or formaldehyde-releasing agents? If yes, how much of the formaldehyde or formaldehyde-releasing agents do they contain?

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10. What are the risks of using hair smoothing or straightening products containing formaldehyde to a stylist? [Probe: eye/skin irritation, coughing, etc.]
11. What about your clients? Are they exposed to the same risks?
12. What precautions do you currently take, if any? [Probe for use of masks, protective glasses, gloves; differentiate between what is used by the stylist and what is used to protect the client or other clients present in the salon.]
13. Are there any types of people you would not perform a hair smoothing treatment on [Probe for: age, pregnant women, poor condition of hair/scalp, etc.]?
14. What kind of training, if any, have you had with regard to hair smoothing treatments?

VI. Evaluation of Labeling Statements [40 minutes]

1. Have you seen any warning labels for hair smoothing products that contain formaldehyde or formaldehyde-releasing agents? Were they located on the bottle itself or elsewhere? What do they say?
2. How often do you read/review them, if at all?
3. What kinds of information do you think should be included in the warning labels for hair smoothing products that contain formaldehyde, or formaldehyde-releasing agents?

[Moderator: please pass around booklets with labeling statements. Ask respondents not to look at all labels, only one at the time as directed by the moderator. Each labeling statement will be presented on an image of a hair smoothing product and as an enlarged text.]

Now, I would like to show you several different warning statements and ask for your reactions. Please look at the first one – Example A – and take a couple of minutes to read it; in the follow-up discussion, I would like to hear your overall impressions. Also, please circle anything you think is critically important, underline anything confusing, cross-out anything you think is not needed, and write down anything you think should be added.

[Moderator: write up instructions on flip chart: 1. CIRCLE what is critically important; 2. Underline anything confusing; 3. Cross-out anything that is not needed; 4. Write down anything that should be added.]

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Example A

WARNING: This product contains methylene glycol and should only be used in a **WELL-VENTILATED** area. When heated, this product releases formaldehyde gas. Exposure to formaldehyde may result in eye and throat irritation, headaches, dizziness, burning sensations, breathing problems, nosebleed, chest pain, and skin irritation.

AVOID PROLONGED OR REPEATED EXPOSURE TO THE PRODUCT. More than one procedure should not be performed at a time. Avoid direct contact with eyes, skin, and mouth. Do not use on hair that is breaking, splitting, shedding, or damaged. If skin contact occurs, wash immediately.

Product **SHOULD NOT** be used on formaldehyde-sensitive individuals or clients with pre-existing medical conditions (e.g. asthma or other respiratory conditions). If product causes skin or scalp irritations, rinse out immediately.

If you are nursing or pregnant do not use the product without first consulting your physician. In the event of illness or medical emergency seek medical attention immediately.

1. What are your overall impressions? [Probe for: what makes the concept appealing or unappealing, what feels most inspiring or motivating for you personally?]
2. What is the main message and for whom is it intended?
3. What did you focus on in the label/what caught your attention?
4. What new facts, if any, did you learn from this statement? [Probe for facts that they did not know before participating in this discussion.]
5. How clear and understandable is this warning? Is it too technical or not technical enough?
6. What is this warning asking you to do? What might you do after seeing this? [Probe: which actions would be easy or hard to do and why, what information or tools that would help people implement the actions suggested in the messages]
7. Using your own words can you explain what the following terms mean to you: 'well ventilated', 'prolonged or repeated exposure', 'ingestion', 'suitable eye and skin protection'. [Moderator: this would allow the opportunity to follow up with asking respondents about their own experiences with respect to ventilation and any adverse effects from using the product to themselves or their clients (if not covered earlier in focus group).]
8. What does this statement make you think of in relation to the safety of this product? Does it provide adequate direction for safe use?
9. What could be done to make it more persuasive?
10. What additional information would you include in the warning statement?

11. What do you think of the way the text is presented? [Probe for: font size, location on the bottle, spacing, symbols, etc.]

Example B

WARNING: This product contains **the chemical** methylene glycol and should only be used in a **WELL-VENTILATED** area. When heated, this product releases formaldehyde gas. Exposure to formaldehyde may result in eye and throat irritation, headaches, dizziness, burning sensations, breathing problems, nosebleed, chest pain, and skin irritation.

AVOID PROLONGED OR REPEATED EXPOSURE TO THE PRODUCT. More than one procedure should not be performed at a time. Avoid direct contact with eyes, skin, and mouth. **Use suitable eye and skin protection when applying and rinsing product to avoid skin and scalp irritation and eye injury.** Do not use on hair that is breaking, splitting, shedding, or damaged. If skin contact occurs, wash immediately.

Product **SHOULD NOT** be used on formaldehyde-sensitive individuals or clients with pre-existing medical conditions (e.g. asthma or other respiratory conditions). If product causes skin or scalp irritations, rinse out immediately.

If you are nursing or pregnant do not use the product without first consulting your physician. If ingestion or eye contact occurs, call a physician immediately. In the event of illness or medical emergency seek medical attention immediately.

Example B is very similar to Example A; the only difference between them is the added words/sentences highlighted in yellow. Please take a moment and look at the added text.

1. What do you think about adding the word “the chemical” before methylene glycol? Does it make a difference? Does it make the statement more or less clear?
2. What about adding the sentence “Use suitable eye and skin protection when applying and rinsing product to avoid skin and scalp irritation and eye injury”? How important is it to add this information?
3. What about adding the sentence “If ingestion or eye contact occurs, call a physician immediately.”? How important is it to add this information?

Example C



WARNING: This product contains methylene glycol and should only be used in a **WELL- VENTILATED** area. When heated, this product releases formaldehyde gas. Exposure to formaldehyde may result in eye and throat irritation, headaches, dizziness, burning sensations, breathing problems, nosebleed, chest pain, and skin irritation.

AVOID PROLONGED OR REPEATED EXPOSURE TO THE PRODUCT. More than one procedure should not be performed at a time. Avoid direct contact with eyes, skin, and mouth. Do not use on hair that is breaking, splitting, shedding, or damaged. If skin contact occurs, wash immediately.

Product **SHOULD NOT** be used on formaldehyde-sensitive individuals or clients with pre-existing medical conditions (e.g. asthma or other respiratory conditions). If product causes skin or scalp irritations, rinse out immediately.

If you are nursing or pregnant do not use the product without first consulting your physician. In the event of illness or medical emergency seek medical attention immediately.

Example C is exactly the same as Example A, except for the symbol that has been added.

[Moderator: This is a universally used symbol signifying hot surface; formaldehyde is released upon the contact of hair smoothing product with hot flat iron.]

1. What do you think about placing a symbol along with a warning statement?
2. What does the symbol bring to mind? In what way, if any, does it change your overall impression of the warning?

Symbols

This is a sheet of different symbols that could be used along with a warning statement.

1. What idea does each of these symbols bring to mind? How understandable would each of them be to a hair stylist like you? Why?/Why not? [Moderator: please elicit responses on each and every symbol on the page.]
2. Which of these symbols would be most appropriate to accompany a warning statement? Why this one? Why not the others?

Example D

WARNING: This product contains methylene glycol and should only be used in a WELL-VENTILATED area. When heated, this product releases formaldehyde gas. Exposure to formaldehyde may result in eye and throat irritation, headaches, dizziness, burning sensations, breathing problems, nosebleed, chest pain, and skin irritation.

AVOID PROLONGED OR REPEATED EXPOSURE TO THE PRODUCT. More than one procedure should not be performed at a time. Avoid direct contact with eyes, skin, and mouth. Do not use on hair that is breaking, splitting, shedding, or damaged. If skin contact occurs, wash immediately.

Product SHOULD NOT be used on formaldehyde-sensitive individuals or clients with pre-existing medical conditions (e.g. asthma or other respiratory conditions). If product causes skin or scalp irritations, rinse out immediately.

If you are nursing or pregnant do not use the product without first consulting your physician. In the event of illness or medical emergency seek medical attention immediately.

Example D is also exactly the same as Example A, except the text at the bottom is placed in a box.

1. What is your impression of placing this text in a box?
2. Would you rather put different information in the box? Why/why not?

Example E

WARNING: This product contains methylene glycol and should only be used in a **WELL-VENTILATED** area. When heated, this product releases formaldehyde gas. Exposure to formaldehyde may result in eye and throat irritation, headaches, dizziness, burning sensations, breathing problems, nosebleed, chest pain, and skin irritation.

- **AVOID PROLONGED OR REPEATED EXPOSURE TO THIS PRODUCT.**
- **More than one procedure should not be performed at a time.**
- **Avoid direct contact with eyes, skin, and mouth.**
- **Do not use on hair that is breaking, splitting, shedding, or damaged.**
- **If skin contact occurs, wash immediately.**

Product **SHOULD NOT** be used on formaldehyde-sensitive individuals or clients with pre-existing medical conditions (e.g. asthma or other respiratory conditions). If product causes skin or scalp irritations, rinse out immediately.

IF YOU ARE NURSING OR PREGNANT, DO NOT USE THIS PRODUCT WITHOUT FIRST CONSULTING YOUR DOCTOR.

In the event of illness or medical emergency, SEEK MEDICAL ATTENTION IMMEDIATELY.

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Example E is also very similar to Example A, but some text was bulleted and the sentence at the bottom has been added.

1. What impression do you get from formatting this text in bullet points?
2. How important, if at all, is it to add this last sentence to the warning statement? Why?

Example F

Caution: This product contains methylene glycol and should only be used in a WELL-VENTILATED area

- **AVOID REPEATED EXPOSURE TO THE PRODUCT**
- **Avoid touching this product or breathing its fumes**
- **Don't do more than one of these treatments at the same time in the same place.**
- **Avoid direct contact with eyes, skin, and mouth. If contact occurs, wash immediately**
- **Do not use on hair that is breaking, splitting, shedding, or damaged.**

Product **SHOULD NOT** be used on people who are sensitive to formaldehyde or have pre-existing medical conditions, such as asthma. If skin or scalp irritation occurs, rinse the product out immediately.

IF YOU ARE NURSING OR PREGNANT, DO NOT USE THIS PRODUCT. DO NOT USE THIS PRODUCT WITHOUT FIRST CONSULTING YOUR DOCTOR.

If you get sick or have a medical emergency when you use this product, get medical attention immediately.

1. What are your overall impressions?
2. What caught your attention?
3. How does it compare to Example A?
4. What are the advantages and disadvantage of this shortened Example F as compared to example A?

Example G

WARNING: This product contains methylene glycol and should only be used in a WELL-VENTILATED area. When heated, this product releases formaldehyde gas. Exposure to formaldehyde may result in eye and throat irritation, headaches, dizziness, burning sensations, breathing problems, nosebleed, chest pain, and skin irritation.

AVOID PROLONGED OR REPEATED EXPOSURE TO THE PRODUCT. More than one procedure should not be performed at a time. Avoid direct contact with eyes, skin, and mouth. Do not use on hair that is breaking, splitting, shedding, or damaged. If skin contact occurs, wash immediately.

Product **SHOULD NOT** be used on formaldehyde-sensitive individuals or clients with pre-existing medical conditions (e.g. asthma or other respiratory conditions). If product causes skin or scalp irritations, rinse out immediately.

If you are nursing or pregnant do not use the product without first consulting your physician. In the event of illness or medical emergency seek medical attention immediately.

In Example G, the frame around the text of the warning has been removed.

1. How does it impact the overall impression of the warning text on the bottle?
2. Does it make the warning stand out more, or does it make it less noticeable?

Example H

WARNING: Product releases formaldehyde gas when treated hair is heated, which may cause short-term and long-term health effects, such as eye, skin, and throat irritation, headache, dizziness, burning sensations, breathing problems, and certain cancers, particularly for those who are sensitive to formaldehyde. This product must be applied by hair professionals only and in conditions that provide adequate ventilation. Concurrent use in the same facility may increase concentration of formaldehyde in the air, which could increase the risk of adverse effects. Avoid unnecessary repeated use.

If you are nursing or pregnant do not use the product without first consulting your physician. If skin contact occurs, wash immediately. If ingestion or eye contact occurs, call a physician immediately. Information on the physical and health hazards, and the safety data sheet, may be obtained from the company.

1. What are your overall impressions?
2. What caught your attention?
3. What new facts, if any, did you learn from this statement?
4. How clear and understandable is this warning? Is it too technical or not technical enough?
5. Does it provide adequate direction for safe use?

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6. What could be done to make it more persuasive? [Probe: what catches your attention, what makes the concept appealing or unappealing, what feels most inspiring or motivating for you personally]
7. What additional information would you include in the labeling statement?
8. How does it compare to Example A?

[Moderator: Ask the following questions after participants have seen and evaluated all warning statements.]

1. Which of these warning statements do you think would be most effective for hair stylists like you? Why?
2. Which of these warning statements do you think would be least effective? Why?
3. How does this label compare to what you currently see?

VII. Evaluation of FDA Web information [10 minute]

Hair-Smoothing Products That Release Formaldehyde When Heated

<http://www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm228898.htm>

[Moderator: pass around printed Web reading material on Formaldehyde, ask respondents to read it swiftly in no more than 5 minutes and ask the questions. Please keep this section brief, it's not a main focus of this discussion.]

1. What is the take away message from this information on Formaldehyde?
2. Who is this information intended for?
3. What is unclear or not understandable?
4. What specific actions, if any, does this information call for?
5. Would you change/add anything?

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[Additional questions from OCAC (3 minutes); will be printed on a sheet of paper to be filled out by the respondents individually.]

1. How important do you consider information about bad reactions and other risks associated with the use of a product? Please mark your response on the scale below where 1 is “not at all important” and 10 is “very important”.

Not important at all										Very important
1	2	3	4	5	6	7	8	9	10	

2. How important is it to include such information on a product label?

Not important at all										Very important
1	2	3	4	5	6	7	8	9	10	

3. How likely would you be to buy /use the product if information about bad reactions and risks associated with the use of the product was declared on a product label?

I would definitely NOT use/buy the product										I would definitely use/buy the product
1	2	3	4	5	6	7	8	9	10	

False Close [5 minutes]

That’s all the questions I have. Do you have any questions for me or any additional feedback that you’d like to provide?

Thank you!

Thank you very much for your time today. Your feedback is very much appreciated.

[Moderator: Stop recording. Administer incentives and obtain receipts.]