

Designation: E 2082 - 00

# Standard Guide for Descriptive Analysis of Shampoo Performance<sup>1</sup>

This standard is issued under the fixed designation E 2082; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon  $(\epsilon)$  indicates an editorial change since the last revision or reapproval.

# 1. Scope

1.1 The objective of this guide is to provide procedures which may be used in the design, execution, and analysis of studies to quantitatively assess the objective sensory attributes of shampoos. This is one of many appropriate techniques used in the hair-care industry. These attributes can then be used to define performance of shampoos and to provide direction in product formulation, research guidance testing, and claim substantiation. This guide includes the sensory properties involved in dispensing a product, as well as the attributes pertinent to shampooing tresses, half and whole heads. Although this guide is specific to shampoos, the procedures should be applicable to most hair-care products.

1.2 Guidelines are provided for the definition of terminology, procedures for manipulation of products, identification/selection of hair type, and judge training. References for rating scales are not provided in this guide. The user should be aware that some sensory practices may require the use of attribute references (anchors) when training the judges.

#### 2. Referenced Documents

2.1 ASTM Standards:

E 253 Terminology Relating to Sensory Evaluation of Materials and Products<sup>2</sup>

2.2 Other Documents:

ASTM Manual 26 Sensory Testing Methods: Second Edition<sup>3</sup>

ASTM STP 758 Guidelines for the Selection and Training of Sensory Panel Members<sup>3</sup>

ASTM Manual 30 Relating Consumer, Descriptive, and Laboratory Data to Better Understand Consumer Responses<sup>3</sup>

ASTM Manual 13 Descriptive Analysis Testing for Sensory Evaluation<sup>3</sup>

21 CFR 50.254

# 3. Terminology

- 3.1 Definitions:
- 3.1.1 *cosmetologist*—a licensed, trained professional who has been certified by state or government agencies to apply hair-care products to human heads. These individuals may be alternately described as beauticians, stylists, hairdressers, or cosmetologists.
- 3.1.2 *subjects*—those individuals recruited to participate in a study for the quality or condition of their hair, to serve as sample carriers.
- 3.1.3 trained panel—a group of judges who have been formally trained to evaluate the visual and tactile properties of shampoo or hair, using a standard descriptive analysis method which quantifies attributes on a rating scale over a set time period. The number may vary depending on the complexity of the test and the skill of the judge.

# 4. Equipment

- 4.1 The following equipment may be used during the evaluation process:
  - 4.1.1 General:
- 4.1.1.1 *Light Source*—A consistent light source is recommended for use during evaluation of shine or luster. It is important to control the amount of light as well as the angle and distance from the hair.
- 4.1.1.2 *Water Source*—Temperature and hardness should be consistent. If controlled temperature sinks are used, they should all have the same, consistent flow rate.
- 4.1.1.3 *Blow Dryer*—Specifications should be documented (that is, wattage, voltage, power level, air velocity, and temperature).
  - 4.1.1.4 Syringes/Pipettes, Petri Dishes.
  - 4.1.1.5 Towels (cloth or paper, or both).
- 4.1.1.6 *Combs*—It is recommended that all combs be identical in material and construction (that is, tooth length, thickness, and distance between teeth). They should be appropriately cleaned before each use. For evaluations on subject heads, combs must be sanitized properly prior to use with each test subject.
  - 4.1.1.7 Thermometer.
  - 4.1.1.8 Hygrometer.
  - 4.1.2 Additional Equipment for Evaluation on Tresses:

<sup>&</sup>lt;sup>1</sup> This guide is under the jurisdiction of ASTM Committee E18 on Sensory Evaluation of Materials and Products and is the direct responsibility of Subcommittee E18.07 on Personal Care and Household Evaluation.

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<sup>&</sup>lt;sup>2</sup> Annual Book of ASTM Standards, Vol 15.07.

<sup>&</sup>lt;sup>3</sup> Available from ASTM Headquarters, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959.

<sup>&</sup>lt;sup>4</sup> Code of Federal Regulations, available from U.S. Government Printing Office, Washington, DC 20402.

- 4.1.2.1 Hair Tresses (also commonly referred to as swatches) (see Section 8 for preparation procedure).
- 4.1.3 Additional Equipment for Evaluation on Subjects (Salon Setting):
  - 4.1.3.1 All-Purpose Styling Chair.
  - 4.1.3.2 *Capes*.
  - 4.1.3.3 Wet/Dry Sanitizers.

# 5. Summary of Guide

- 5.1 This guide provides guidelines for the identification, selection, and training of judges, using a common procedure, so they may effectively evaluate the sensory attributes of shampoos and the effects of their use on hair. This guide describes the evaluation using hair tresses and subjects (half and whole heads).
- 5.2 During tress evaluation, a panel of trained judges treats hair swatches with the shampoo products, and evaluate the appearance, product pick-up, application, foaming, and wet hair and dry hair attributes of the shampoo.
- 5.3 Evaluations using live subjects are typically performed in a salon-type setting. In some cases, the services of a licensed cosmetologist may be required by state or local law. Licensed cosmetologists may bring an expanded frame of reference and may be trained as descriptive judges. Many of the attributes evaluated on subject heads are similar to those evaluated on tresses.
- 5.4 A comparative overview highlighting the characteristics of shampoo evaluation using tresses and using live subjects is provided in the following chart:

Comparative Overview of Shampoo Testing Using Trained Evaluators Tresses versus Subjects Subject: Half or Whole Head

Less Controlled:

Less Artificial:

conditions

Initial Investment:

station

ness, damage, etc.)

specific hair types

Controlled procedure but highly

variable hair/scalp types and condi-

tions (length, diameter, oiliness, dirti-

• In special cases, may screen/target

· Scalp/sebum involvement, packing/

whole-head effects, usually incorpo-

· Higher capital requirements per

Requires suitable salon-style

facilities/stations with controlled lighting, water flow, etc.

May require fewer total stations

rates a range of hair types/

Tress

Highly Controlled Testing:

- · Controlled procedure, limited variability
- · Uniform hair samples (typically commercially blended "virgin" hair)
- Often may purchase/create desired/ target hair types

Artificial:

 Lack scalp/sebum involvement packing/scalp orientation effects, single hair type represented

Initial Investment:

- Lower capital requirements per
- · Controlled environment should include controlled lighting, water flow, and individual panelist stations
- · Several approaches available, varying in sophistication and expense
- · Depending on testing volume and scheduling, may require a greater total number of stations

Initial Training and Maintenance:

- · Variable, but probably grossly similar for tress and subject testing Lower Cost for Testing:
  - Judge fees, consumables (syringes,
  - · Hair reuseable over extended periods

Initial Training and Maintenance:

- · Variable, but probably grossly similar for tress and subject testing Higher Cost for Testing:
  - In addition to judges fees and consumables; there are subject fees, recruiting costs
  - May require services of a licensed cosmetologist for some types of

Sample Turn Around:

Comparative Overview of Shampoo Testing Using Trained Evaluators Tresses versus Subjects

Tress

· Rapid testing, high throughput, judges available as needed - little to no lead time

Evaluations/Evaluators:

· Typically requires fewer total evaluations but more (minimum of 7 to 10) evaluators, usually 2 or more reps/

Subject: Half or Whole Head

· Less rapid testing, judges available, but may require additional lead time for subject recruiting

Evaluations/Evaluators:

- · Requires more total evaluations (subjects), but may require fewer trained panelists (see 10.1)
- · Simultaneous descriptive and subiect self-assessment possible

# 6. Significance and Use

- 6.1 The methods outlined in this guide can be used to qualitatively and quantitatively describe the performance and sensory characteristics of shampoos.
- 6.2 The methods described in this guide may be used for product formulation and research guidance as well as for quality control.
- 6.3 These methods may be used by individuals who familiarize themselves with these procedures and who have previous experience with sensory evaluation.
- 6.4 Variables that may affect results include, but are not limited to, water conditions (for example, hardness), hair type, and hair condition. These variables should be controlled or accounted for in the experimental design.
- 6.5 These are suggested procedures and are not intended to exclude alternate methods, which may effectively provide the same or similar results.

#### 7. Trained Panel Selection and Descriptive Training

- 7.1 The objective is to select and train judges to evaluate the visual and tactile properties of shampoos on hair tresses using a descriptive analysis method. The selection process should include the principles embodied in ASTM STP 758. The task of the judge is to describe product and hair attributes by rating the perceived quantity and quality of specified attributes.
  - 7.2 Trained Panel Selection:
- 7.2.1 Panelists may be recruited from within the company, or from the local community. The use of licensed cosmetologists as trained panelists adds an additional qualification to the community recruit.
- 7.2.2 The choice to use internal employees allows a company to have panelists on site and control proprietary information. It may, however, create potential resource and scheduling conflicts, since panel evaluation will not be the employees' primary job focus.
- 7.2.3 The use of local community residents allows the company to schedule more panel time per week and may lower the risk of losing panelists. A large pool of potential judges is usually available.
- 7.2.3.1 A screening questionnaire is recommended to determine availability, interest, general knowledge of tactile properties, ability to use descriptive words, and ability to use rating scales. Some questions on the screening questionnaire relate to previous and current employment. These questions may conflict with individual company policy (see Table 1).
- 7.2.4 With specific training, licensed cosmetologists may represent a special type of descriptively trained panelist. In some states, licensing is required to apply certain hair-care products to live models (subjects). Information concerning the

Sample Turn Around:



# TABLE 1 Screening Questionnaire

Nan	ne Phone No					
Add	ress (city/state) (zip code)					
GEN	NERAL:  Are you currently employed outside the home? Yes ( ) No ( ) If yes, what hours and days do you work					
2.	Are there any weekdays (Monday through Friday) that you are NOT available on a regular basis? Please list the hour(s) and day(s) you are committed:					
3.	Do you have your own transportation? Yes ( ) No ( )					
4.	Do you or any member of your immediate family work for a consumer product manufacturer, a marketing research firm, or advertising company?  Yes ( ) No ( )					
HEA	ALTH:					
1.	Have you ever had an allergic or adverse reaction to a shampoo, hair rinse, soap, or any hair-care or cleanser product? Yes ( ) No ( ) If yes, please describe					
2.	Do you have any of the following?  Yes  No					
	Psoriasis ( ) ( )					
	Eczema ( ) ( )					
	Central nervous system disorder ( ) ( )					
	Unusually cold or warm hands ( ) ( ) Skin rashes ( ) ( )					
	Calluses on hands/fingers ( ) ( )					
	Hypersensitive skin ( ) ( )					
	Tingling in the fingers					
3.	List the name of any medications you are currently taking:					
TOL	JCH QUIZ: (please answer each question in your own words)					
1.	What tactile characteristics of a lotion would make you think it is rich?					
2.	What is thicker, an oily or greasy film?					
3.	When you rub an oily film on your skin, how do you fingers move?  Slip or Drag (check one)					
4.	What properties make a tissue feel soft?					
5.	How might the appearance of a hand creme influence your perception of the feel of it?					
6.	Name some things that are sticky?					
7.	When your skin feels moist, what other words or properties could describe it?					
8.	Name some things that are rough					
	What makes them rough?					
9.	Briefly, how would you define absorbent in a lotion?					
10.	What properties make a deodorant feel sticky?					

legal requirements for licensing professional cosmetologists may be obtained through the states' Board of Beauty Culture.

- 7.2.5 Licensed cosmetologists typically will require higher compensation than non-licensed candidates. Since licensed cosmetologists are experienced, they may require a shorter training period. They may also have some preconceived biases.
- 7.2.6 When cosmetologists are trained as descriptive evaluators, the difference between their traditional role and their role as a trained descriptive evaluator should be carefully explained.
  - 7.3 Recruitment and Screening:
- 7.3.1 A large group of candidates may be recruited from the local community or from within the company (50 to 70 recommended, with necessarily fewer if licensed cosmetologists are to be used) by contacting community groups, placing newspaper adds, interoffice memos, or notices posted on bulletin boards.
- 7.3.2 Prior to completing a screening questionnaire, the time commitment for training (orientation and practice sessions), potential duration of the panel, panel objectives, and panelist commitment should be discussed with each candidate. In addition, in the case of a cosmetologist panelist, the differences between conduct and responsibilities as a trained evaluator and those of a cosmetologist should be emphasized.
- 7.3.3 A screening questionnaire is recommended (refer to 7.2.3.1).
- 7.3.4 Select 15 to 20 panelists. This number may vary depending on the complexity of the test and the skill of the panelists. The following criteria may be used as a guideline. Other approaches are described in ASTM Manual 13 and ASTM STP 758.
  - 7.3.4.1 *Screening Questionnaire*:
- (a) (a) Availability for the complete orientation and 80–100 % of the training practice sessions.
- (b) (b) No health-related problems, such as, skin irritations, central nervous system disorders, or medications which might interfere with the central nervous system or reduce skin and muscle activity.
- (c) (c) Correct and comprehensive descriptive answers to 75 % or more of the open-ended tactile questions in the screening questionnaire.
- (d) (d) Correct rating of 80 % or more of the scaling exercises in the screening questionnaire (see Fig. 1 and Fig. 2).
- 7.3.4.2 *Interview*—Each candidate should be interviewed by the panel administrator or trainer to determine attitude, interest, and ability to learn and work in a group situation. The candidate should demonstrate good verbal skills, a high interest in descriptive dynamics, and a cooperative yet confident personality (see Table 2).
  - 7.4 Trained Panel Orientation/Training:
- 7.4.1 The panel trainer needs to orient panelists first to the general concepts, such as, the definition, components, and application of descriptive analysis testing. This will take approximately two hours.
- 7.4.2 Panelists are introduced to the need for strictly controlled sample application procedures and for the careful definition of each sensory attribute. This will take approximately two hours.

#### SCALING EXERCISE

INSTRUCTIONS: LOOK AT THE FIGURE ON THE LEFT. DETERMINE THE AMOUNT THAT IS SHADED. PLACE A MARK ON THE SCALE AT THE RIGHT TO INDICATE THE PROPORTION OF THE AREA THAT IS SHADED.

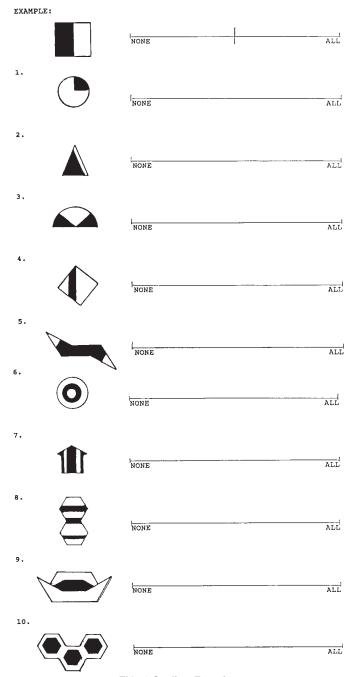


FIG. 1 Scaling Exercise

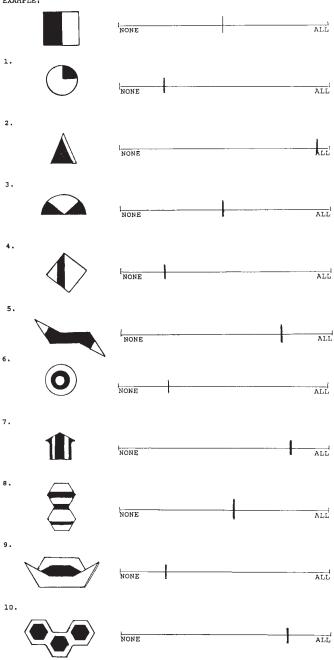
7.4.3 A discussion and demonstration of each attribute is conducted at each stage of the evaluation. This establishes the overall structure of the descriptive analysis of hair-care properties. Panelists are encouraged to discuss each term, its definition, the evaluation procedure(s), and the corresponding rating scale after they are demonstrated by the panel trainer. The time involved completing this step depends on the number of attributes selected and the length of discussions. See Section 9 for suggested procedures and attributes.

#### SCALING EXERCISE

INSTRUCTIONS:

LOOK AT THE FIGURE ON THE LEFT. DETERMINE THE AMOUNT THAT IS SHADED. PLACE A MARK ON THE SCALE AT THE RIGHT, TO INDICATE THE PROPORTION OF THE AREA THAT IS SHADED.

EXAMPLE:



7.4.4 For each attribute, the procedure, definition, and scale are discussed again in greater depth. Each is demonstrated again with three references when possible. References should represent the full intensity range from none to high. The time involved completing this step will again depend on the number of attributes selected.

FIG. 2 Key for Scaling Exercise

7.4.5 The attributes (characteristics) and procedures identified in this guide are suggested (see Section 9). Additional

attributes may be observed, identified, and evaluated by different panels. Individual panels may choose to rename the attributes.

#### 7.5 Trained Panel Practice:

- 7.5.1 Several practice sessions totaling at least 20 to 24 h should be conducted to review the orientation material. These sessions should include reviewing the procedure, definition and rating scale for each attribute, and the evaluation of one or two products using the scale references.
- 7.5.2 During the practice sessions, five to six pairs of samples should be evaluated on all attributes for each stage. The initial pairs of samples should be very different from each other. This will take from ten to twelve hours.

## 7.6 Trained Panel Validation:

- 7.6.1 If possible, correlate results from a recently trained panel to results from an established panel. Otherwise, panel performance can be validated by comparing the results of replicate evaluations. For this purpose, each test material should be presented a minimum of three times.
- 7.6.2 Alternate methods of validation may be suitable. Refer to ASTM Manual 30, ASTM Manual 26, ASTM Manual 13, or ASTM STP 758, or combination thereof, for a more detailed discussion on panel validation.
- 7.7 Trained Panel Monitoring—Several different aspects can be monitored when reviewing panel and panelist's data.
- 7.7.1 A measure of the variability among the panelists can be determined with three replications of three samples for all attributes and all panelists. This permits the panel leader to determine if one or more panelist is (a) rating consistently higher or lower than the panel as a whole on one or more attributes, (b) rating all products consistently the same, (c) rating over a larger or smaller range than other panelists, or (d) rating products as opposite in intensity to the rest of the panel. If inconsistency is noted, a review of definitions, evaluation procedure, or reference standards, or combination thereof, are recommended.
- 7.7.2 A measure of the reproducibility of the panel as a whole can be monitored by analyzing three replications of the panel's evaluation of two or three samples of the same product type. Each attribute should be examined.
- 7.7.3 Refer to ASTM Manual 26 for more detailed information on statistical procedures for sensory evaluation.

# 8. Preparation Procedures for Using Hair Tresses

- 8.1 These procedures are designed for the evaluation of shampoos on hair tresses and can be used with a trained panel or a cosmetologist, or both.
- 8.2 Tresses should be from the same bundle or lot number, and should be checked for uniformity and quality.
- 8.3 Hair tresses should be mounted to a tab or other fastening device. The hair should be cut to the same length, approximately 15 to 25 cm. Depending on the test, the hair should be washed with either a standard non-conditioning shampoo or detergent solution (for example, 5 % TEA lauryl sulfate or 15 % sodium lauryl sulfate). The tresses should be dried at room temperature. Preparation of the tresses should include orientation of the hair in the same direction (root to tip) to avoid tress to tress differences from frictional effects created by the cuticle scales during combing.

#### **TABLE 2 Interview Questionnaire**

Nar	ne	Date	
1.	Are you comfortable working in a group situation?		
2.	How do you feel about voicing your opinion?		
3.	How do you feel about opinionated people?		
4.	How do you feel about committing your time to a training program?		
5.	Are you interested in being a panelist?		
6.	Do you have any questions for me?		
Cor	nments		
Acc	repted: YES NO		

8.4 The hair tresses should be preconditioned prior to use. This would require storing the tresses in an area in which the temperature and humidity are controlled (and recorded) until equilibration.

8.5 Prior to evaluation, judges should wash their hands with a 5 % aqueous solution of a surfactant such as TEA lauryl sulfate in a standard manner at the test facility. Immediately following, hands should be rinsed with tepid tap water and dried thoroughly with absorbent paper towels.

8.6 The temperature level and if possible, the relative humidity of the panel room should be maintained at a constant comfortable level. Room lighting should be consistent for each panelist and remain standard within a given test.

8.7 For each evaluation, the panel leader should dispense a uniform amount, such as 1.0 mL, of the shampoo sample from a syringe or repeater pipette. Presentation of samples should be balanced and blinded. Syringes or pipettes should be loaded immediately prior to their use.

# 9. Evaluation Procedures for Use With Hair Tresses

9.1 Appearance Characteristics—Panel trainer dispenses a circle (2 cm in diameter) of each shampoo onto a petri dish for the evaluator(s) to observe. Products should be packaged and dispensed from the same type of container or dispenser, such as a syringe or repeater pipette. The amount dispensed should be controlled as well as the speed or force with which it is dispensed. The distance and angle from dispense to the dish surface should be controlled. Evaluate for visual firmness, integrity of shape, intensity of color, brightness of color, transparency, gloss, and pearlescence.

Visual firmness
(immediate)

degree to which the product mounds, not spreads, as it is dispensed onto the dish
(soft/liquid......firm)

degree to which the product holds its original shape in the dish (This is related to visual firmness, however, integrity of shape provides information on the effect of time.)

(none/looses shape......high/maintains shape)

Intensity of color	strength of color from light to dark
	(lightdark)
Brightness of color	chroma (or purity) of the color, ranging from dull,
•	muddled to pure, bright color (for example, fire engine red is brighter than burgundy)
	(dullbright)
Transparency	degree to which light passes through the sample or prod- uct
	(opaqueclear/transparent)
Gloss	degree to which the sample reflects light
	(nonehigh)
Pearlescence	degree of mother of pearl-like or opalescent character
	(nonehigh)

9.2 *Pickup Characteristics*—The panel leader delivers a controlled amount of product to the thumb of each evaluator. The evaluator compresses the product between the thumb and forefinger three times, opening and closing fingers to a predetermined distance. The tempo or speed should be controlled. Evaluate for firmness, stickiness, and stringiness.

Firmness force required to compress the product between the fingers (low.....high/firm)

Stickiness force required to separate the fingers (low....high/sticky)

Stringiness amount the product strings or stays connected when the fingers are separated. (low...high/stringy)

9.3 Application and Foam Characteristics—A standard amount of product is dispensed onto a wet hair tress. The procedure for wetting the tress and the placement of the product on the tress should be uniform. The evaluator should use a standard procedure for spreading the product, handling the tress, and manipulating the subsequent foam. Evaluate for ease of spreading, speed to foam, amount of foam, cushion of foam, bubble size, and wetness of foam. Rinse product from fingers for predetermined number of seconds under running water. Rinse tress and evaluate for ease of rinsing.

Ease of spreading ease of distributing the product evenly over the surface of the hair prior to generating the foam (not easy/difficult.....easy)

Speed to foam	measure of the time or degree of manipulation required to generate foam
	(slowfast)
Amount of foam	assessment of the volume of foam after each of several
	points
	(nonehigh)
Cushion of foam	measure of the force to compress the foam between the
	thumb and forefinger
	(nonehigh)
Wetness of foam	amount of moisture perceived in the foam mass
	(drywet)
Bubble size	visual size of the majority of bubbles
	(smalllarge)
Ease of rinsing	time to rinse product out of tress under controlled condi-
_	tions (water pressure and temperature)
	(record time or count)

9.4 Wet Hair Characteristics—The hair tress should be towel dried to remove excess water. Using a standard comb, hold hair tress at the top in one hand, with opposite hand comb from the top of the hair tress down to the end of the tress. Evaluate for ease of detangling and force to comb. Hold wet hair tress loosely in a closed fist, rub hair between thumb and index finger in a downward motion. Evaluate for wet feel/slipperiness and residue.

Ease of detangling	ease of removing the tangles from the hair tress (not easy/difficulteasy)
Force to comb	force applied to the comb to move it through the hair tress. Apply and measure only the minimum and necessary force.
	(nonehigh)
Wet feel/Slipperiness	presence or absence of resistance when moving the fingers down the hair between the thumb and forefinger (dragslip)
Residue (greasy/oily/ waxy)	total amount of all residues left on hair (tactile sensation). The individual types of residues may be identified and quantified.
	(nonehigh)

9.5 Dry Hair Characteristics—Dry tress in a standard, controlled manner (for example, hanging in a hood dryer or using a hand-held blow dryer). The same drying procedure should be used by each evaluator. Hold the dry tress at the top in one hand. With the opposite hand hold the comb by the end. Comb the hair tress starting at the top and moving down. Evaluate for ease of detangling and force to comb. Hold dry tress loosely in a closed fist, rub hair between thumb and index finger in a downward motion. Evaluate for dry feel/slipperiness, residue and pliability. Continue to comb in a vigorous manner. Evaluate for static. (For static evaluation, specify either the number of strokes or amount of time to comb.)

Ease of detangling
Force to comb

Series (same as for wet hair characteristics)

However, the hair is evaluated in sections (for example, middle section, ends).

Dry feel/slipperiness
Residue

Pliability

Static

Series (same as for wet hair characteristics)

(same as for wet hair characteristics)

(same as for wet hair characteristics)

measure of the force required to bend the hair, not stiff or rigid

(low.....high)

Static

# 10. Evaluation of Half and Whole Heads/Subject Selection

10.1 Due to the large amount of variation from subject to subject, a minimum of 20 subjects is usually required. This is highly dependent on the study objective, the number of evaluators, and other practical constraints.

- 10.2 Subjects may be recruited from within a company or from the local community.
- 10.3 Subjects, those individuals who will serve as sample carriers, should be selected based on the objective of the test or target population of the product (for example, age, sex, hair type), or both.
- 10.4 Based on the objective of the study inclusion or exclusion, or both, criteria may be selected from the suggested pre-evaluation form (see Table 3). The pre-evaluation form, if used, should be completed for each subject by the evaluator prior to the start of each test. It is possible in some cases to include instrumental evaluations to assess the condition of the hair prior to treatment. The type of instrument, procedure, readings, and interpretation for each subject should be documented.
- 10.5 It may also be useful to have the subject complete a record of personal habits and practices. For certain tests, subjects may be selected based on hair type, condition of hair, product use or those representative of a particular segment of the population, or combination thereof. These forms can be kept on file and should be updated periodically.
- 10.6 A medical history should be recorded and kept on file for each subject (see Table 4). For each test, all subjects should be asked if their medical history has changed since they last participated in a shampoo evaluation. A medical history should be updated as needed when there is a change in the medical history of a returning subject.
- 10.7 In addition, informed written consent must be obtained from all subjects prior to participation. The consent must include the basic elements of informed consent as specified by the Federal Register (21 CFR 50.25).
- 10.8 Some reasons not to accept a subject might include: extremes in hair condition that are not representative of the population, hair type, or extremely asymmetrical hair cut that can be problematic for half head evaluation.
- 10.9 The hair condition of subjects who participate frequently should be monitored for overuse.

#### 11. Evaluation Procedure Using Half-Heads

- 11.1 The following procedure is designed for the in-use evaluation of two shampoos on wet hair of half-heads. Either a sequential monadic or a paired comparison method can be used and should be determined by the test objective. For a sequential monadic, one half of the hair is washed and evaluated in steps independent of the other side. For a paired comparison, both sides are washed at the same time using a different shampoo product on each side.
- 11.2 The evaluator should wash their hands in a standard manner. A 5 % aqueous solution of a surfactant such as TEA Lauryl Sulfate is recommended. Thoroughly dry hands (see 8.5).
- 11.3 Appearance Characteristics—The evaluator dispenses a controlled or measured amount of shampoo onto the hand. Product assignment should be done in accordance with the handedness of the evaluator to avoid the inherent variability in force applied. Evaluate for ease of dispensing, integrity of shape, intensity of color, brightness of color, transparency and gloss. See 9.1 for definitions and scales. Rewash hands as described in 8.5.



#### TABLE 3 Preevaluation of Hair and Scalp

Subject Name:	Date:				
Age:	Birth Date:	Rac	e:	Sex:	
Condition of hair shaft:	very dry □	moderately dry □	normal 🗆	moderately oily □	very oily □
Condition of hair ends:	very dry □	moderately dry	normal □	moderately oily $\square$	very oily □
Cleanliness of hair:	very dirty □		somewhat dirty $\square$		very clean □
Shine:	very dull □		medium $\square$		very shiny □
Density:	thin 🗆		medium $\square$		thick
Texture:	very fine □	fine □	medium $\square$	coarse □	wiry 🗆
Length: (longest section)	inches				
Color:	natural color	cur	rent color		
Color treatment:	natural 🗆	tinted	semi-permanent	permanent	frosted
	other $\square$				
Amount of hair color treated:	%				
Amount of gray hair:	%				
Wave treatment:	no ☐ yes ☐ Date of las	st perm	permanent □	straightened	
	Area treated:				
Amount of hair permed:	%				
Degree of curl:	none □				very curly $\square$
Natural Afro:	no □ yes □				
Scalp condition:	no flakes □				very flaky □
	dry (not oily) $\square$				very oily □
Other scalp conditions:					
Has there been a change in the	medical condition since the last vis	it: no □ yes □	]		
Recommendation:	Continue	Discontinue			
Examiner Signature		/_ Date			

- 11.4 Pickup Characteristics—The panel leader delivers a controlled amount of product to the thumb of each evaluator. The evaluator compresses the product between the thumb and forefinger three times, opening and closing fingers to a predetermined distance. The tempo or speed should be controlled. Evaluate for firmness, stickiness, and stringiness. See 9.2 for definitions and scales. Rewash hands as described in 11.2.
- 11.5 Thoroughly wet hair on the entire head. Part hair down the middle of the head from the forehead to the nape of the neck.
- 11.6 Dispense sample of shampoo from a syringe directly onto the hair on one side of the head. The quantity of product may vary according to hair length, density, and product type. A

- 5.0-mL application per side is suggested for the first shampoo and 2.5 to 3.0 mL if a second shampoo is conducted.
- 11.7 *In-Use Evaluation*—Shampoo by rotating hands vigorously, with an equal number of strokes and equal amount of pressure. The number of rotations or length of manipulation should be controlled (for example, 5 to 10 rotations or 15 s). Evaluate for ease of spreading and speed to foam. Squeeze the fingers together on the last rotation through the hair and pull through the hair on both sides, stripping the foam with the closed fingers. Observe and record the amount of foam, cushion of foam, bubble size, and wetness of foam. Turn the subject's head slightly to the left side and thoroughly rinse foam from front hairline to back of ear for a standard length of



#### **TABLE 4 Medical History**

Subject Name:						Date:	
Age:	Birth Da	te:		Race:		Sex:	
Do you currently have o	r have you ever exp	erienced any of the following	ng?				
			YES	NO			
Asthma							
Hay fever							
		ling of nasal mucosa,					
	, itching eyes, watery	eyes)					
Allergy to house d							
Allergy to animal h	nair						
Allergy to food(s)							
Other allergies							
,		)					
Dermatitis							
Psoriasis							
Eczema					\/F0	NO.	
Have you over had a re-	action from the use	of hair products such as sh	omnoo oon	ditionara bair annov gal	YES	S NO	
		ons, or any fragrances?	iampoo, con	ullioners, nair spray, ger	5,		
mousses, nair uye, pe	illialielit wave solut	ons, or any nagrances?			_		
If yes, please explain							
Do you currently have o	r have you ever had	any scalp problems?					
If yes, please explain							
Are you currently under	the care of a physic	an?					
If yes, condition being tr	eated for						
		LIST ALL CURRENT	MEDICATION	ONS (OTC OR PRESCR	RIPTION)		
Drug Nar	me	Indication		Dosage	е	Start	Date
Drug Hai		maleation		Dosage	,	Otari	Saic
		·					
Subject Signature		Date		Examiner Signature		Da	te

time (for example, 15 s) using agitation with fingertips at the same time. Evaluate for ease of rinsing. (See 9.3 for definitions and scales.) Repeat the procedure for the opposite side.

11.8 Instruct the subject to sit upright while the hair is gently towel dried. Reestablish the part from the forehead to nape.

11.9 Wet Hair Evaluation—Using a standard comb, begin combing the left side of the head. Start from the center of the crown, comb from the scalp, behind the ear to the ends. Continue to the back of the head. After a minimum of 5 strokes, evaluate for the ease of detangling and force to comb. Place one hand over one side of the head. Taking a lock of hair between the thumb and index finger, slide finger along shaft of hair from the scalp to the ends. Run hands and fingertips through the hair four times. Evaluate slip and residue. (See 9.4 for definitions and scales.) Repeat the procedure for the opposite side.

11.10 *Dry Hair Evaluation*—Completely dry the subject's hair. A uniform system for drying hair should be followed throughout the test. When possible, the wattage/velocity should be controlled. Using a standard comb begin combing one side of the head. Start from the center of the crown, comb from the

scalp to the ends. Continue to the back of the head. A minimum of five strokes per side are required. Evaluate for ease of detangling. After completely removing the tangles, using the end of a standard comb, evaluate force to comb and static. Proceed with feel assessment by placing one hand over the side of the head. Taking a lock of hair between the thumb and index finger, slide fingers along shaft of hair from the scalp to the ends. Run hands and fingertips through the hair four times. Observe and record smoothness, residue, pliability, body/fullness, and sheen/luster. (See 9.5 for the definitions and scales not listed as follows.) Repeat the procedure for the opposite side.

Smoothness amount of or lack of a rough, harsh feeling along the hair shaft (harsh/rough......smooth)

Body/fullness degree to which the hair feels full; volume of hair (low.....high)

Sheen/luster amount of light reflected off the hair. (low.....high)

11.11 Styling Evaluation—Using an electric curling iron, curl 1 to 3 curls on each side of the head. Hair should be curled using the same curling iron and same curling time. Using a standard comb, comb the curl from the scalp to the ends.

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Evaluate for resiliency, ease of styling, and sheen/luster. (See 11.10 for the definitions and scales not listed as follows.) Repeat the procedure for the opposite side.

Resiliency ability of hair to revert back to its curled state after

combing

(loose curl.....tight curl)

Ease of styling ease in which the hair can be combed and placed as

desired

(not easy/difficult....easy)

11.12 Because of the variability of the hair between subjects, it is important to have an experimental design that takes this potential confound (treatment effect not due to an independent variable but to an overlooked factor) into consideration.

11.13 A post evaluation at 6, 12, and 24 h (or some other appropriate time interval) may be done. Follow the procedures identified in 11.11. No other treatments should be used on the hair prior to the evaluations.

### 12. Evaluation Procedures Using Whole Heads

- 12.1 The following procedure variation is designed for the in-use evaluation of shampoo on wet hair as a whole head. This procedure is a variation of the half-head procedure described in Section 11, and may be used when the half-head procedure is not appropriate or practical.
- 12.2 The whole-head procedure may be used to assess and develop a descriptive profile of a shampoo's performance in a monadic design. It may also be used to provide comparative results when a sequential monadic design is employed.

12.3 The basic procedure for whole-head assessments is essentially identical to the half-head procedure. The basic differences are that the hair is not parted down the middle and an overall assessment of both sides is made. Product quantities for the evaluation must be modified (for example, 10.0 mL for the first shampoo and 5.0 mL for the second shampoo).

# 13. Report

- 13.1 It is recommended that a final report be issued to the project leader or requester. Report the following elements:
- 13.1.1 *Summary*—A brief statement of the test objectives, results, and conclusions.
- 13.1.2 *Objectives*—An overview of project objectives/test objectives agreed upon before the start of the experiment.
- 13.1.3 *Methodology*—A presentation of the procedure(s) used
- 13.1.4 Equipment, Materials, and Test Products—A list of key items used to conduct the test and identification of the test articles.
- 13.1.5 *Results*—A presentation and summary of the relevant collected data and statistical analysis.
- 13.1.6 *Conclusions*—An interpretation as to the theoretical and practical relationship to previous knowledge.

### 14. Keywords

14.1 descriptive analysis; hair; hair-care products; panelists; sensory; shampoo; tactile

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