

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

This standard is issued under the fixed designation E2082; 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  $(\varepsilon)$  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 swatches, 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 assessor 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 assessors.

#### 2. Referenced Documents

2.1 ASTM Standards:<sup>2</sup>

E253 Terminology Relating to Sensory Evaluation of Materials and Products

2.2 ASTM Publications:<sup>3</sup>

ASTM Manual 13 Descriptive Analysis Testing for Sensory Evaluation

ASTM Manual 26 Sensory Testing Methods: Second Edition ASTM Manual 30 Relating Consumer, Descriptive, and Laboratory Data to Better Understand Consumer Responses ASTM STP 758 Guidelines for the Selection and Training of Sensory Panel Members

2.3 Code of Federal Regulations:<sup>4</sup>

21 CFR 50.25 Protection of Human Subjects—Elements of Informed Consent

#### 3. Terminology

- 3.1 *Definitions*—Definitions of terms other than those given as follows appear in Terminology E253.
  - 3.2 Definitions:
- 3.2.1 *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.
- 3.2.2 *subjects*—those individuals recruited to participate in a study for the quality or condition of their hair, to serve as sample carriers.
- 3.2.3 trained panel—a group of assessors 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 assessor.

#### 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.

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<sup>&</sup>lt;sup>2</sup> For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

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

<sup>&</sup>lt;sup>4</sup> Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401.

- 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 Swatches:
- 4.1.2.1 Hair 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 assessors, 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 swatches and subjects (half and whole heads).
- 5.2 During swatch evaluation, a panel of trained assessors 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 assessors. Many of the attributes evaluated on subject heads are similar to those evaluated on swatches.
- 5.4 A comparative overview highlighting the characteristics of shampoo evaluation using swatches and using live subjects is provided in the following chart:

Comparative Overview of Shampoo Testing Using Trained Evaluators Swatches versus Subjects

#### Swatch

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

Subject: Half or Whole Head Less Controlled:

- · Controlled procedure but highly variable hair/scalp types and conditions (length, diameter, oiliness, dirtiness, damage, etc.)
- In special cases, may screen/target specific hair types
- Less Artificial:

· Scalp/sebum involvement, packing/whole-head effects. usually incorporates a range of hair types/conditions

Comparative Overview of Shampoo Testing Using Trained Evaluators Swatches versus Subjects

#### Swatch

Initial Investment:

- Lower capital requirements per station
- · Controlled environment should include controlled lighting, water flow, and individual assessor 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 swatch and subject testing

#### Lower Cost for Testing:

- Assessor fees consumables (syringes, etc.)
- · Hair reusable over extended periods

#### Sample Turn Around:

· Rapid testing, high throughput, assessors 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/product

#### Subject: Half or Whole Head Initial Investment:

- Higher capital requirements per station
  - · Requires suitable salon-style facilities/stations with controlled lighting, water flow, etc.
  - · May require fewer total stations

#### Initial Training and Maintenance:

 Variable, but probably grossly similar for swatch and subject testing

#### Higher Cost for Testing:

- In addition to assessors' fees and consumables; there are subject fees, recruiting costs
- May require services of a licensed cosmetologist for some types of testing

#### Sample Turn Around:

 Less rapid testing, assessors available, but may require additional lead time for subject recruiting Evaluations/Evaluators:

### Requires more total evaluations (subjects), but may require fewer trained assessors (see 10.1)

· Simultaneous descriptive and subject 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 assessors to evaluate the visual and tactile properties of shampoos on hair swatches using a descriptive analysis method. The selection process should include the principles embodied in ASTM STP 758. The task of the assessor 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 Assessors may be recruited from within the company, or from the local community. The use of licensed cosmetologists as trained assessors adds an additional qualification to the community recruit.

- 7.2.2 The choice to use internal employees allows a company to have assessors 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 assessors. A large pool of potential assessors 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. This questionnaire is used to eliminate unsuitable candidates. Some questions on the screening questionnaire relate to previous and current employment. Assess if any of these questions conflicts with individual company policy (see Table 1) It is recommended that the form be approved by the company's human resources department.
- 7.2.4 With specific training, licensed cosmetologists may represent a special type of descriptively trained assessor. In some states, licensing is required to apply certain hair-care products to live models (subjects). Information concerning the 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). If candidates are recruited from the local community, recommendations include contacting community groups, placing newspaper ads, and an announcement on the recruiting company's website. If candidates are recruited within the company, interoffice memos or emails, or notices posted on the company's website or bulletin boards are effective.
- 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 assessor commitment should be discussed with each candidate. In addition, in the case of a cosmetologist assessor, 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 assessors. This number may vary depending on the complexity of the test and the skill of the assessors. 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:

- (1) Availability for the complete orientation and 80–100 % of the training practice sessions.
- (2) 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.
- (3) Correct and comprehensive descriptive answers to 75 % or more of the open-ended tactile questions in the screening questionnaire.
- (4) 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 assessors 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 Assessors 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.
- 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. Assessors 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.
- 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.
- 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:



# **TABLE 1 Screening Questionnaire**

Nan	ne Phone No					
Add	ress(city/state) (zip code)					
GEN 1.	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 ( ) ( )					
	ringing in the ingers					
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 cream 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?					

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

#### SCALING EXERCISE SCALING EXERCISE INSTRUCTIONS: LOOK AT THE FIGURE ON THE LEFT. DETERMINE THE INSTRUCTIONS: LOOK AT THE FIGURE ON THE LEFT. DETERMINE THE AMOUNT THAT IS SHADED, PLACE A MARK ON THE SCALE AMOUNT THAT IS SHADED. PLACE A MARK ON THE SCALE AT THE RIGHT TO INDICATE THE PROPORTION OF THE AREA AT THE RIGHT, TO INDICATE THE PROPORTION OF THE AREA THAT IS SHADED. THAT IS SHADED. EXAMPLE: EXAMPLE: NONE ALL NONE ALL 1. 1. NONE NONE ALL ALL 2. 2. NONE ALL NONE 3. 3. ALL NONE ALL NONE 4. NONE NONE ALL ALL 5. 5. NONE ALL NONE ALL 6. 6. NONE NONE ALL ALL 7. 7. NONE ALL NONE 8. 8. ALL NONE NONE ALL'

FIG. 1 Scaling Exercise

NONE

NONE

9.

10.

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 assessors' data.

7.7.1 A measure of the variability among the assessors can be determined with three replications of three samples for all attributes and all assessors. This permits the panel leader to determine if one or more assessor is (I) rating consistently higher or lower than the panel as a whole on one or more attributes, (2) rating all products consistently the same, (3) rating over a larger or smaller range than other assessors, or (4) rating products as opposite in intensity to the rest of the panel.

FIG. 2 Key for Scaling Exercise

NONE

NONE

ALL

ALL

9.

10.

ALL

ALL



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

Nan	ne	Date		
	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 an assessor?			
6.	Do you have any questions for me?			
Con	Comments			

Accepted: YES NO

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 Swatches

- 8.1 These procedures are designed for the evaluation of shampoos on hair swatches and can be used with a trained panel or a cosmetologist, or both.
- 8.2 Swatches should be from the same bundle or lot number, and should be checked for uniformity and quality.
- 8.3 Hair swatches 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 swatches should be dried at room temperature. Preparation of the swatches should include orientation of the hair in the same direction (root to tip) to avoid swatch to swatch differences from frictional effects created by the cuticle scales during combing.
- 8.4 The hair swatches should be preconditioned prior to use. This would require storing the swatches in an area in which the temperature and humidity are controlled (and recorded) until equilibration.
- 8.5 Prior to evaluation, assessors 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 assessor 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 Swatches

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/liquidfirm)
Integrity of shape (10-15 s)	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/loses shapehigh/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 product
Gloss	(opaqueclear/transparent) degree to which the sample reflects light (nonehigh)



Pearlescence degree of mother of pearl–like or opalescent character (none.....high)

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 swatch. The procedure for wetting the swatch and the placement of the product on the swatch should be uniform. The evaluator should use a standard procedure for spreading the product, handling the swatch, 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 swatch and evaluate for ease of rinsing.

ease of distributing the product evenly over the surface Ease of spreading of the hair prior to generating the foam (not easy/difficult..... Speed to foam measure of the time or degree of manipulation required to generate foam (slow.....fast) Amount of foam assessment of the volume of foam after each of several points (none..... Cushion of foam measure of the force to compress the foam between the thumb and forefinger (none.....high) Wetness of foam amount of moisture perceived in the foam mass Bubble size visual size of the majority of bubbles (small.....large) Ease of rinsing time to rinse product out of swatch under controlled conditions (water pressure and temperature) (record time or count

9.4 Wet Hair Characteristics—The hair swatch should be towel dried to remove excess water. Using a standard comb, hold hair swatch at the top in one hand, with opposite hand comb from the top of the hair swatch down to the end of the swatch. Evaluate for ease of detangling and force to comb. Hold wet hair swatch 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 swatch (not easy/difficulteasy)
Force to comb	force applied to the comb to move it through the hair swatch. 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/Silicone)	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 swatch 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 swatch at the top in one hand. With the opposite hand hold the comb by the end. Comb the hair swatch starting at the top and moving down. Evaluate for ease of detangling and force to comb. Hold dry swatch 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

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

Dry feel/slipperiness
Residue
(same as for wet hair characteristics)
Residue
(same as for wet hair characteristics)
measure of the force required to bend the hair, not stiff or rigid
(low.....high)
Static

(same as for wet hair characteristics)
measure of the force required to bend the hair, not stiff or rigid
(low.....high)

# 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, gender, 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 It is recommended that the medical history form be approved by the company's human resources department. Completed medical forms 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.



#### **TABLE 3 Preevaluation of Hair and Scalp**

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

- 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. A5 % 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



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

Subject Name:				Date	e:
Age:	Birth Date:		Race:	Gender:	
Do you currently have	e or have you ever experienced any of the fo	llowing?			
		YES	NO		
Asthma					
Hay fever					
Non rhinitis (syr	nptoms: sneezing, swelling of nasal mucosa,				
nasal dischar	ge, itching eyes, watery eyes)				
Allergy to house	e dust				
Allergy to anima	al hair				
Allergy to food(s	5)				
Other allergies					
	)				
Dermatitis					
Psoriasis					
Eczema					
				YES	NO
	reaction from the use of hair products such a		tioners, hair spray, gels,		
mousses, hair dye,	permanent wave solutions, or any fragrance	s?			
If you places evaluin					
ii yes, piease expiairi					
Do you currently have	e or have you ever had any scalp problems?				
If yes, please explain					
Are you currently und	er the care of a physician?				_
If yes, condition being	treated for				
	LIST ALL CURF	RENT MEDICATION	NS (OTC OR PRESCRI	PTION)	
Drug N	Name Indication	n	Dosage		Start Date
			·		
					/
Subject Signature	Date	E	xaminer Signature		Date

shape, intensity of color, brightness of color, transparency and gloss. See 9.1 for definitions and scales. Rewash hands as described in 8.5.

- 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. These amounts should be adjusted depending on hair length.
- 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 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, and use a separate clean unused comb identical in appearance to the one used on the left 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 of the hair drying system 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, using a separate comb.

Smoothness	amount of or lack of a rough, harsh feeling along the shaft	ha
	(harsh/roughsmooth)	
Body/fullness	degree to which the hair feels full; volume of hair	
	(lowhigh)	
Sheen/luster	amount of light reflected off the hair.	
	(lowhigh)	

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. 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	liency ability of hair to revert back to its curled state afte combing		
Ease of styling	(loose curltight contains in which the hair can be combed and place		
	desired (not easy/difficulte	asv)	

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. Subject self-assessments might be needed in some of these time intervals, when return to a facility may not be practical. 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 assessors; descriptive analysis; hair; hair-care products; sensory; shampoo; tactile



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