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Final Report on the Safety Assessment of Potassium-Coco-Hydrolyzed Animal Protein and Triethanolamine-Coco-Hydrolyzed Animal Protein

Potassium and TEA-Coco-Hydrolyzed Animal Proteins (PCHAP and TEA-CHAP) are salts of the condensation product of coconut acid and hydrolyzed animal protein. They are used in cosmetic products as detergents, foamers, and levelers.

Acute oral toxicity studies showed that both PCHAP and TEA-CHAP were practically nontoxic when ingested. Both ingredients at concentrations of 10%–100% were practically nonirritating to moderately irritating when instilled in the eyes of rabbits. Both were nonirritating to mildly irritating when applied at concentrations of 10%–50% to the skin of rabbits. Guinea pig sensitization studies with both PCHAP and TEA-CHAP were negative.

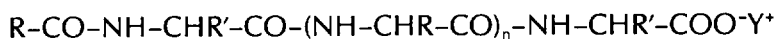
PCHAP and TEA-CHAP, at concentrations of 2%–10% were nonirritating to practically nonirritating in humans. In a repeated insult patch test, PCHAP gave a positive sensitization reaction in two of 168 subjects; two additional subjects showed cumulative irritation and one other was reported to have a nonspecific irritation. One subject out of 28 tested did not demonstrate significant irritation or sensitivity to either PCHAP or TEA-CHAP, but was photosensitized to both ingredients.

On the basis of the available information, the Panel concludes that Potassium-Coco-Hydrolyzed Animal Protein and TEA-Coco-Hydrolyzed Animal Protein are safe as cosmetic ingredients in the present practices of use as recorded in this report.

CHEMISTRY

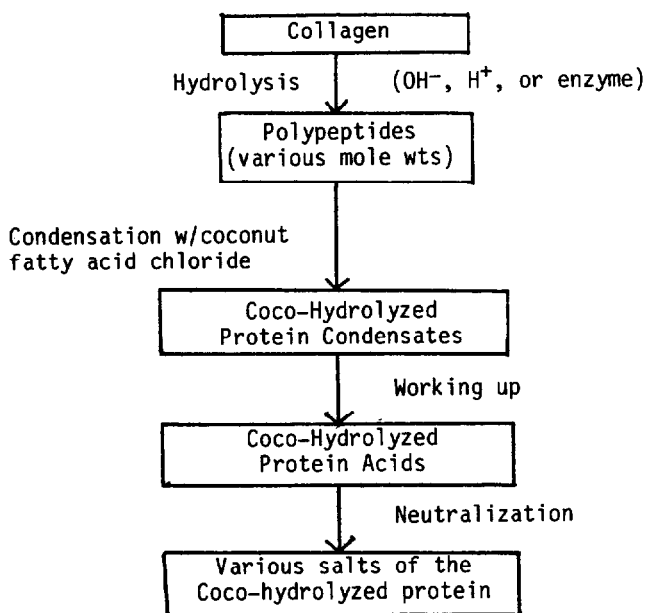
Structure

Potassium and Triethanolamine-Coco-Hydrolyzed Animal Proteins (PCHAP and TEA-CHAP, respectively) are salts of the condensation product of coconut acid and hydrolyzed animal protein. Each conforms to the structure:⁽¹⁾



where R-CO represents the acyl moiety of coconut fatty acid; R' represents the carbon chains of the mixed amino acids and polypeptides found in collagen (predominantly glycine, proline, alanine, and hydroxyproline); and Y⁺ represents the potassium or TEA cation.

Chrome-leather splittings are used as a collagen source.⁽²⁾ This protein material is hydrolyzed by acid, base, or enzymes into short-chained polypeptides. Due to random bond breaking during this step, polypeptide chains vary in length and molecular weight. Fatty acid chlorides (i.e., coconut fatty acid) are then added, forming amide linkages with the free amino groups on the polypeptide chain. The ratio of polypeptide to fatty acid changes with increasing molecular weight of the product. For molecular weights less than 600, fatty acids predominate, whereas at molecular weights greater than 600, the polypeptide predominates. In the final step of production, the terminal carboxyl group of the fatty acid is neutralized with either potassium or TEA ions to form a salt. The reaction temperature for preparing this ingredient varies between 60° and 100°C.⁽²⁾ A typical manufacturing process of coco-hydrolyzed animal proteins is shown below.^(3,4)



Properties

PCHAP and TEA-CHAP are clear to slightly hazy amber liquids. Table 1 lists some chemical and physical properties of these coco-hydrolyzed animal proteins. Each ingredient has unique properties which are dependent upon the proportions of polypeptide and fatty acid in the product.⁽⁴⁾

Viscosity of fatty acid hydrolyzed animal proteins is dependent on various conditions. Viscosity is high under conditions of low pH and low molecular weight (lower fatty acid content) and increases with time which may be a result of the orientation of the fatty acid.⁽⁴⁾

Coco-hydrolyzed animal proteins exhibit good foaming and detergent properties. As anionic tensides, their cleansing effect is dependent on low molecular weight and low pH conditions.⁽⁴⁾

These ingredients increase the skin and eye compatibility of anionic-active tensides (i.e., sodium laureth sulfate) without interfering with the cosmetic properties. The foaming and cleansing properties of sodium laureth sulfate were undisturbed by the addition of fatty acid hydrolyzed animal protein.⁽⁴⁾

Impurities and Additives

The impurities reported in PCHAP (in order of predominance) include: coconut fatty acid, hydrolyzed animal protein (collagen) and inorganic salts (sodium chloride, sodium sulfate, potassium chloride, and potassium sulfate).⁽¹⁾

Impurities reported in TEA-CHAP (in order of predominance) include: coconut fatty acid, hydrolyzed animal protein (collagen), triethanolamine sulfate, sodium chloride, and sodium sulfate.⁽¹⁾ There were no reports of potential chemical interactions of either PCHAP or TEA-CHAP with other cosmetic ingredients. It is suspected that in the presence of nitrite and other nitrosating agents cosmetic preparations containing TEA-CHAP may give rise to N-nitrosodiethanolamine.

COSMETIC USE

Coco-hydrolyzed animal proteins are used in cosmetics as detergents, foamers, and levelers. In shampoos, the protective colloidal action of the

TABLE 1. Properties.

| Property | PCHAP | TEA-CHAP |
|-------------------------|--|--|
| Solids (%) ^a | 30%–38% | 32%–40% |
| Ash (%) | 7% maximum | 0.8% maximum |
| Water (%) | 70% maximum | 60%–62% |
| pH | 6.0–7.5 | 6.7–7.3 |
| Possible additives | Ethylparaben, formaldehyde, sodium polyphosphate | Ethylparaben, formaldehyde, sodium polyphosphate |

^aOf the two suppliers of PCHAP and TEA-CHAP, the American manufacturer lists percent solids as 30%–38% and 32%–40%, respectively, while the German tab states that both ingredients contain 32% solids.

Data from Refs. 1,3.

polypeptide moiety prevents excessive defatting while the detergent activity produces good cleansing action.⁽³⁾

According to the industry's voluntary submissions to the Food and Drug Administration (FDA) in 1981, PCHAP is used in 251 cosmetic formulations. A concentration range of >25%–50% was reported for two shampoos and one skin

TABLE 2. Product Formulation Data.

| Product category | Total no. of formulations in category | Total no. containing ingredient | No. product formulations within each concentration range (%) | | | | | |
|--|---------------------------------------|---------------------------------|--|--------|-------|------|--------|------|
| | | | >25-50 | >10-25 | >5-10 | >1-5 | >0.1-1 | ≤0.1 |
| PCHAP | | | | | | | | |
| Bubble baths | 475 | 6 | — | — | — | 6 | — | — |
| Other bath preparations | 132 | 1 | — | — | — | 1 | — | — |
| Hair conditioners | 478 | 4 | — | — | 1 | 2 | 1 | — |
| Hair straighteners | 64 | 12 | — | — | — | — | 3 | 9 |
| Permanent waves | 474 | 55 | — | — | — | 6 | 48 | 1 |
| Hair shampoos (noncoloring) | 909 | 33 | 2 | 1 | 8 | 13 | 7 | 2 |
| Tonics, dressings, and other hair grooming aids | 290 | 6 | — | — | — | 2 | 3 | 1 |
| Wave sets | 180 | 1 | — | — | — | 1 | — | — |
| Other hair preparations (noncoloring) | 177 | 3 | — | — | — | 3 | — | — |
| Hair dyes and colors (all types requiring caution statement and patch test) | 811 | 43 | — | — | 5 | 38 | — | — |
| Hair lighteners with color | 2 | 1 | — | — | — | 1 | — | — |
| Hair bleaches | 111 | 1 | — | — | — | 1 | — | — |
| Nail polish and enamel | 767 | 74 | — | — | — | — | — | 74 |
| Other manicuring preparations | 50 | 6 | — | — | — | 3 | — | 3 |
| Skin cleansing preparations (cold creams, lotions, liquids, and pads) | 680 | 3 | 1 | — | — | 2 | — | — |
| Face, body, and hand skin care preparations (excluding shaving preparations) | 823 | 1 | — | — | — | 1 | — | — |
| Other skin care preparations | 349 | 1 | — | — | — | — | 1 | — |
| 1981 TOTALS | | 251 | 3 | 1 | 14 | 80 | 63 | 90 |
| TEA-CHAP | | | | | | | | |
| Hair conditioners | 478 | 3 | — | — | — | 3 | — | — |
| Hair shampoos (noncoloring) | 909 | 11 | 1 | — | 1 | 1 | 7 | 1 |
| Tonics, dressings, and other hair grooming aids | 290 | 1 | — | — | — | 1 | — | — |
| Cuticle softeners | 32 | 1 | — | — | — | — | — | 1 |
| Bath soaps and detergents | 148 | 1 | — | — | — | 1 | — | — |
| Other skin care preparations | 349 | 1 | — | — | — | 1 | — | — |
| 1981 TOTALS | | 18 | 1 | — | 1 | 7 | 7 | 2 |

Data from Ref. 5.

cleansing cream. PCHAP is most commonly used in hair preparations. TEA-CHAP was reported in 18 formulations, usually in concentrations of up to 5%. Like PCHAP, it is generally found in hair preparations. A concentration range of >25%–50% was reported for one shampoo. Table 2 summarizes product formulation data for these two ingredients.⁽⁵⁾

The cosmetic product formulation computer printout which is made available by the FDA is compiled through voluntary filing of such data in accordance with Title 21 part 720.4 of the Code of Federal Regulations (1979). Ingredients are listed in prescribed concentration ranges under specific product type categories. Since certain cosmetic ingredients are supplied by the manufacturer at less than 100% concentration, the value reported by the cosmetic formulator may not necessarily reflect the actual concentration found in the finished product; the concentration in such a case would be a fraction of that reported to the FDA. The fact that data are submitted only within the framework of preset concentration ranges also provides the opportunity for overestimation of the actual concentration of an ingredient in a particular product. An entry at the lowest end of a concentration range is considered the same as one entered at the highest end of that range, thus introducing the possibility of a two- to 10-fold error in the assumed ingredient concentration.

Formulations which contain PCHAP or TEA-CHAP may come into contact with the face, hair and scalp, nails, axillae, and skin. These products are used daily or occasionally and their use may extend over years. Contact with formulations containing PCHAP or TEA-CHAP may last from seconds to several days.⁽⁵⁾

BIOLOGICAL PROPERTIES

General Effects

Collagen is often the protein used for hydrolysis in the preparation of these ingredients. This is partly because of its nonantigenic properties. Topical, intradermal, and subcutaneous sensitivity tests using collagen polypeptides (MW 110–1400) were performed on 50 male and 50 female guinea pigs. No antigenic responses or sensitivity resulted.⁽⁴⁾

Various ratios of sodium laureth sulfate to protein fatty acid condensates were tested for sucrase inhibition. Inhibition was nearly 100% for pure sodium laureth sulfate; however, when diluted to 60% or less with protein fatty acid condensate, there was no inhibition. Additionally, protein fatty acid condensates (at various molecular weights) were tested alone for sucrase inhibition. At molecular weights of 550 and 650, inhibition was negligible (3.5% and 0.5%, respectively) and nonexistent at molecular weights of 750, 900, and 1200.⁽⁴⁾

The adverse biological properties of protein fatty acid condensates include diminution of alkaline neutralization power of the skin, alteration of epidermal pH and eye irritation. Eye irritation appears to be inversely proportional to the molecular weight of the condensate and to the ratio of polypeptides in the product.⁽⁴⁾

Animal Toxicology

Acute Oral Toxicity

PCHAP and TEA-CHAP were tested for acute oral toxicity. Data are presented in Table 3. These studies indicate that PCHAP and TEA-CHAP are practically nontoxic when administered orally at the dosages specified.⁽⁶⁻⁸⁾

Acute Irritation

Ocular

Both PCHAP and TEA-CHAP were tested for rabbit eye irritation. Each ingredient was tested at 10%, 25%, 50%, and 100% concentrations. One-tenth ml of the test material at each dilution was instilled into one eye of six rabbits; the contralateral eye served as the control. Observations were made at 1, 2, and 8 h and each day for one week. Solutions containing 10% TEA-CHAP or PCHAP were reported to be minimally irritating with the most irritation (conjunctival only) subsiding by the second day of testing. Solutions containing 25% TEA-CHAP or PCHAP were defined as mildly irritating. Irritation disappeared after the second day. At a concentration of 50%, TEA-CHAP and PCHAP also caused mild irritation; however, irritation (corneal and conjunctival) lasted the duration of the experiment. Undiluted PCHAP and TEA-CHAP caused moderate irritation which also lasted the duration of the testing. Table 4 summarizes the results.⁽⁹⁻¹²⁾

In other studies, both PCHAP and TEA-CHAP were tested at concentrations of 10% and 100% for eye irritation. The Draize method was used as the test procedure, but an unknown method was used for scoring irritation. Each ingredient, at a concentration of 10%, caused minor conjunctival irritation which cleared by 72 h. The authors concluded that these materials were "practically nonirritating" at the concentration tested.^(13,14) When the undiluted ingredient was instilled

TABLE 3. Acute Oral Toxicity of Coco-Hydrolyzed Animal Proteins.

| <i>Ingredient</i> | <i>Dose (per kg)</i> | <i>No. of rats</i> | <i>Oral LD50 (per kg)</i> | <i>Ref.</i> |
|-------------------|--------------------------|------------------------|-------------------------------|-------------|
| PCHAP | 10.0 g | 10 | No deaths | 6 |
| PCHAP | 10.4–29.5 g | 20 | 18.2 g ^a | 7 |
| PCHAP | 10 or 20 ml | 10 | No deaths | 8 |
| PCHAP | 10 or 20 ml | 10 | No deaths | 8 |
| TEA-CHAP | 15.89–44.9 g | 20 | 27.3 g ^b | 7 |
| TEA-CHAP | 10 or 20 ml | 20 | No deaths | 8 |
| TEA-CHAP | 10 or 20 ml | 20 | No deaths | 8 |

^aOf the dead animals, the following observations were made: hyperemic lungs; "bleached" liver, kidneys and spleen; gastrointestinal tracts distended with sample; bloody nasal discharge; diuresis; hyperemic gastrointestinal tract and hardened sample in stomach. Of the survivors: five with red spotted lungs at dosage 10.4 ml/kg. Organs of the thorax and abdomen normal in others.

^bOf the dead animals, the following observations were made: hyperemic lungs; "bleached liver and kidneys"; hyperemic gastrointestinal tract distended with sample; darkened spleen; hemorrhage of the gastrointestinal tract; bloody nasal discharge; diureseis and darkened liver.

TABLE 4. Eye Irritation.

| <i>Ingredient</i> | <i>Concentration (%)</i> | <i>1 h</i> | <i>2 h</i> | <i>8 h</i> | <i>1 day</i> | <i>2 days</i> | <i>3 days</i> | <i>4 days</i> | <i>5 days</i> | <i>6 days</i> | <i>7 days</i> | <i>Area(s) affected</i> |
|-------------------|--------------------------|------------|------------|------------|--------------|---------------|---------------|---------------|---------------|---------------|---------------|-------------------------|
| PCHAP | 10 | 7.33 | 9.33 | 9.33 | 3.00 | 0.67 | 0 | 0 | 0 | 0 | 0 | Conjunctivae |
| PCHAP | 10 | 6.33 | 8.00 | 5.67 | 0.67 | 0 | 0 | 0 | 0 | 0 | 0 | Conjunctivae |
| PCHAP | 25 | 12.00 | 14.33 | 10.67 | 2.33 | 0 | 0 | 0 | 0 | 0 | 0 | Conjunctivae |
| PCHAP | 25 | 17.33 | 18.67 | 16.00 | 10.67 | 0.67 | 0 | 0 | 0 | 0 | 0 | Cornea and conjunctivae |
| PCHAP | 50 | 11.33 | 14.33 | 14.67 | 4.83 | 4.33 | 1.17 | 0 | 0 | 0 | 0 | Cornea and conjunctivae |
| PCHAP | 50 | 15.33 | 15.67 | 15.00 | 14.50 | 7.50 | 1.33 | 0 | 0 | 0 | 0 | Cornea and conjunctivae |
| PCHAP | 100 | 10.33 | 13.33 | 11.33 | 8.83 | 3.33 | 0.33 | 0.33 | 0 | 0 | 0 | Iris and conjunctivae |
| PCHAP | 100 | 16.67 | 17.00 | 16.00 | 13.00 | 18.00 | 26.17 | 21.17 | 24.50 | 14.17 | 2.83 | All |
| TEA-CHAP | 10 | 7.33 | 8.33 | 6.67 | 2.00 | 1.00 | 0 | 0 | 0 | 0 | 0 | Conjunctivae |
| TEA-CHAP | 10 | 5.00 | 7.67 | 5.33 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Conjunctivae |
| TEA-CHAP | 25 | 12.67 | 14.33 | 13.00 | 6.00 | 0 | 0 | 0 | 0 | 0 | 0 | Conjunctivae |
| TEA-CHAP | 25 | 14.33 | 16.00 | 14.67 | 5.67 | 1.00 | 0 | 0 | 0 | 0 | 0 | Conjunctivae |
| TEA-CHAP | 50 | 10.67 | 13.00 | 12.00 | 1.67 | 0.33 | 0.33 | 0.33 | 0 | 0 | 0 | Conjunctivae |
| TEA-CHAP | 50 | 13.33 | 16.33 | 15.00 | 18.50 | 9.00 | 2.67 | 2.67 | 1.00 | 0.67 | 0.67 | Cornea and conjunctivae |
| TEA-CHAP | 100 | 13.67 | 17.00 | 29.50 | 12.50 | 5.33 | 3.33 | 3.00 | 3.00 | 2.17 | 1.50 | Cornea and conjunctivae |
| TEA-CHAP | 100 | 14.66 | 15.33 | 16.00 | 22.83 | 16.33 | 2.67 | 1.33 | 0.33 | 0.67 | 0 | Cornea and conjunctivae |

Based on the method of Draize (total possible score = 110).

Data from Refs. 9–12.

into eyes of rabbits, severe irritation developed in the cornea, iris, and/or conjunctiva. Irritation persisted throughout the 72 h observation period. These ingredients were considered to be eye irritants.^(7,15)

Skin

Primary Irritation: PCHAP and TEA-CHAP were tested for potential skin irritancy in rabbits. The Draize method was used in all studies. PCHAP was reported to be nonirritating to slightly irritating when applied at a 10% concentration. Undiluted PCHAP was mildly irritating; erythema was the only skin response observed. At a concentration of 10%, TEA-CHAP was determined to be nonirritating to rabbits' skin. Undiluted TEA-CHAP was found to be slightly to mildly irritating in two studies; however, erythema, edema, and eschar formation were reported in one study which concluded that undiluted TEA-CHAP is severely irritating (PII = 3.05; maximum score = 8). Results of these tests are summarized in Table 5.^(6-9,13)

Sensitization: PCHAP (0.1 ml of a 0.1% solution) was administered intracutaneously to the shaved skin of two white male guinea pigs. The injections were made every other day, three times weekly, until a total of 10 injections had been administered. Two weeks after the final induction injection, a challenge injection of 0.05 ml of the solution was made. Skin sites were scored 24 h following every injection and challenge scores were compared with induction scores. PCHAP elicited no responses to either induction or challenge injections and was considered to be nonsensitizing under the test conditions.⁽⁶⁾

Two samples each of PCHAP and TEA-CHAP at 10% were tested for potential sensitization according to the Buehler method. No reactions to test or challenge patches occurred in any of the guinea pigs (20 per ingredient). Both ingredients were considered to be nonsensitizing in all four tests at the given concentration.⁽⁹⁾

TABLE 5. Primary Skin Irritation.^a

| <i>Ingredient</i> | <i>No. of rabbits</i> | <i>Concentration (%)</i> | <i>PII^b</i> | <i>Reactions</i> | <i>Comment</i> | <i>Ref.</i> |
|-------------------|-----------------------|--------------------------|------------------------|-----------------------------------|---------------------|-------------|
| PCHAP | 6 | 10 | 0.00 | — | Nonirritating | 8 |
| PCHAP | 6 | 10 | 0.50 | erythema | Slightly irritating | 8 |
| PCHAP | 6 | 100 | 1.59 | erythema | Mildly irritating | 9 |
| PCHAP | 6 | 100 | 1.26 | erythema | Mildly irritating | 9 |
| PCHAP | 6 | 100 | 1.04 | erythema | Mildly irritating | 6 |
| PCHAP | 6 | 100 | 1.88 | eschar formation | Mildly irritating | 7 |
| TEA-CHAP | 6 | 10 | 0.00 | — | Nonirritating | 8 |
| TEA-CHAP | 6 | 10 | 0.00 | — | Nonirritating | 8 |
| TEA-CHAP | 6 | 100 | 1.21 | edema and erythema | Mildly irritating | 9 |
| TEA-CHAP | 6 | 100 | 0.50 | erythema | Slightly irritating | 9 |
| TEA-CHAP | 6 | 100 | 3.05 | eschar formation, edema, erythema | Severely irritating | 7 |

^aMethod and scoring according to Draize.

^bPrimary Irritation Index (Maximum Score = 8).

CLINICAL ASSESSMENT OF SAFETY

Single Insult Patch Test

Patch tests were performed on 33 subjects using PCHAP at concentrations of 2% and 20%. Occlusive patches containing PCHAP at each concentration were applied to the chest or arm, and left in place for 24 h. Sites were scored upon patch removal and at 48 and 72 h. No reactions occurred.⁽¹⁶⁾

In another study, PCHAP and TEA-CHAP were simultaneously tested on 50 subjects. Two samples of each ingredient were tested at a concentration of 10%. Of the 50 subjects tested, at least eight had skin diseases (psoriasis and eczema) and many were being treated for illnesses (i.e., migraines, allergies, diabetes). There were 29 healthy subjects. Approximately 1.5 mg/cm² of each ingredient were applied under patches and left in place for 24 h. Sites were scored upon removal and at 48 and 72 h. One reaction (slight erythema at 24 h from a patch containing 10% PCHAP) occurred in a patient with psoriasis.⁽¹⁷⁾ Table 6 summarizes the results of these studies.

Sensitization

A 5% solution of a soap containing 41%–43% PCHAP was used by a "large number of healthy subjects and people suffering from dermatitis" over a 10- to 48-day period. Histological examinations of the treated area indicated a low irritation frequency and no signs of sensitivity.⁽¹⁸⁾

A repeated insult patch test was performed on 168 subjects (115F, 53M) using 0.1 ml of a 10% water solution of PCHAP and TEA-CHAP. The test material was applied at 48 h intervals, three times per week for three weeks on the subjects' backs. The test area was occluded for 24 h, removed, and washed with distilled water. The test sites were read at 48 h, after which fresh test material and the occlusive patch were reapplied. After a three-week rest period, the test area, as well as a virgin site, were challenged using the same procedure as previously noted. The sites were scored for sensitization at 24, 48, and 72 hours. Five subjects challenged with PCHAP were reported to have significant erythema, and were rechallenged at concentrations of 2.5%, 5.0%, and 10.0%. The rechallenge was scored at 24, 48, and 72 h. The results of both the initial challenge and subsequent rechallenge indicated that PCHAP produced allergic contact sensitization in two subjects, cumulative irritation in two additional subjects, and a mild

TABLE 6. Single Insult Patch Test (Human).

| <i>Ingredient</i> | <i>Concentration (%)</i> | <i>No. of subjects</i> | <i>Subject ages (yrs)</i> | <i>M/F</i> | <i>No. of reactions</i> | <i>Comments</i> | <i>Ref.</i> |
|-------------------|--------------------------|------------------------|---------------------------|------------|-------------------------|--------------------------------|-------------|
| PCHAP | 2 | 33 | 20–76 | 18/15 | 0 | nonirritating | 16 |
| PCHAP | 20 | 33 | 20–76 | 18/15 | 0 | nonirritating | 16 |
| PCHAP | 10 | 50 | 15–59 | 22/28 | 0 | nonirritating | 17 |
| PCHAP | 10 | 50 | 15–59 | 22/28 | 1 | 1* erythema at 24 h, 0 at 48 h | 17 |
| TEA-CHAP | 10 | 50 | 15–59 | 22/28 | 0 | nonirritating | 17 |
| TEA-CHAP | 10 | 50 | 15–59 | 22/28 | 0 | nonirritating | 17 |

nonspecific irritation in a fifth subject. The two subjects who were sensitized to PCHAP were also sensitized to TEA-CHAP.⁽¹⁹⁾

Phototoxicity

One percent water solution of PCHAP and TEA-CHAP was tested on ten subjects under the regulations of the German Association for Light Research.⁽²⁰⁾ The investigator reported no UVB phototoxicity and no UVA phototoxicity when the treated skin was exposed to 7.5 J/cm² (15 min PUVA 6001).

Twenty-eight of the 168 subjects tested for irritation and sensitization discussed above were randomly selected to test the ability of PCHAP and TEA-CHAP to induce a phototoxic or photosensitive reaction following ultraviolet exposure. The test protocols were the same except that the forearm was used as a test site. The 28 subjects were divided into two groups; 19 received only UVA and 9 received both UVA and UVB. The UVA (320–400 nm) light was applied for 15 min to the 19 subjects (4.4 μ W/cm² at the skin surface measured at a 360 nm wavelength peak). The UVB was applied at two times Mean Erythema Dose (MED) to nine subjects from a 150 watt Xenon Arc Solar Simulator emitting at 280–320 nm. The subjects receiving the UVB exposure were also exposed for 5 min to UVA as previously described. One subject included in the photosensitization subgroup reported above was sensitized to both PCHAP and TEA-CHAP. One additional subject who was considered by the investigator to be photosensitized by both PCHAP and TEA-CHAP at the original challenge site at 72 h. Only TEA-CHAP gave a similar value for this subject when challenged at a virgin site.⁽¹⁹⁾

Worker/Consumer Experiences

A chemical manufacturer has stated that he and his predecessor have produced protein derivatives for 40 years. During that time, there has been no case of sensitization or allergenic reaction by workers involved in the handling of these products.⁽²¹⁾

Approximately 600,000 units of a shampoo containing 1% TEA-CHAP have been sold without report of consumer complaint.⁽²²⁾

SUMMARY

Potassium and TEA-Coco-Hydrolyzed Animal Proteins are salts of the condensation product of coconut acid and hydrolyzed animal protein. These two ingredients are prepared by the hydrolysis of collagen to short-chained polypeptides, then addition of coconut fatty acid and finally neutralization of the terminal carboxyl group of the fatty acid with either potassium or TEA. These ingredients have chemical and physical properties which are dependent upon their ratios of fatty acid to polypeptides. PCHAP is used in 251 and TEA-CHAP is used in 18 cosmetic products as detergents, foamers and levelers. Both ingredients are reported to be used primarily in rinse-off products, with one exception being a skin cleansing preparation.

Acute oral toxicity studies reveal that both PCHAP and TEA-CHAP are practically nontoxic when ingested. Both ingredients at concentrations of 10%–100% were practically nonirritating to moderately irritating when instilled in the eyes of rabbits. Both were nonirritating to mildly irritating when applied at concentrations of 10%–50% to the skin of rabbits. Guinea pig sensitization studies concluded that PCHAP and TEA-CHAP are nonsensitizing.

PCHAP and TEA-CHAP, at concentrations of 2%–10%, were nonirritating to practically nonirritating (one reaction in 50 subjects) when tested using a single insult patch test and a total of 266 patches.

In a repeated insult patch test PCHAP gave a positive sensitization reaction in two of 168 subjects; two additional subjects showed cumulative irritation and one other was reported to have a nonspecific irritation. The two subjects reported to be sensitized to PCHAP were also sensitized to TEA-CHAP. One subject out of 28 tested did not demonstrate significant irritation or sensitivity to either PCHAP or TEA-CHAP, but was photosensitized to both ingredients.

CONCLUSION

On the basis of the available information, the Panel concludes that Potassium-Coco-Hydrolyzed Animal Protein and TEA-Coco-Hydrolyzed Animal Protein are safe as cosmetic ingredients in the present practices of use as recorded in this report.

ACKNOWLEDGMENT

Mr. Kevin Fisher, Scientific Analyst and writer, prepared the technical analysis used by the Expert Panel in developing this report.

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