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Final Report on the Safety Assessment of Cetearyl Octanoate

Cetearyl Octanoate is the esterification product of 2-ethylhexanoic acid and cetearyl alcohol. The acute oral LD50 for Cetearyl Octanoate is estimated from studies with rats to be greater than 8.0 ml/kg. The ingredient produced no significant acute, subchronic or dermal skin or eye irritation when tested in rabbits. The ingredient produced no evidence of skin sensitization in the guinea pig. Similar studies with product formulations containing Cetearyl Octanoate confirmed these results, as well as indicated the ingredient was not phototoxic.

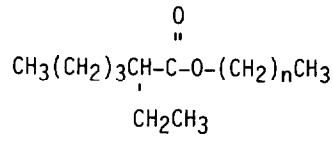
In clinical studies, four of 100 subjects showed slight to moderate irritation with undiluted Cetearyl Octanoate. Product formulations containing between 0.2% and 30% Cetearyl Octanoate were tested on a total of 644 subjects with no signs of skin sensitization, photocontact allergenicity, or phototoxicity.

From the available information, it is concluded that Cetearyl Octanoate is safe as a cosmetic ingredient in the present practices of use.

CHEMISTRY

Structure and Physical Properties

CETEARYL Octanoate is the ester of cetearyl alcohol, a mixture of fatty alcohols which consists predominantly of cetyl and stearyl alcohols, and 2-ethylhexanoic acid. The ingredient is a mixture of branched chain fatty esters which conform to the general formula:



where n is predominantly 15 and 17.[1-3]

Other names include Cetyl/Stearyl 2-Ethylhexanoate, PCL Liquid, and Pur-Cellin Oil.

Cetearyl Octanoate is commercially produced by catalytic esterification with removal by azeotropic distillation.[1] It is also prepared by blending cetyl octanoate and stearyl octanoate in a weight ratio of 7:2, which gives some indication of its ester composition.[4]

The ingredient is a clear, oily liquid with properties similar to those of the oil secreted by the preen glands of waterfowl.[5] It is soluble in absolute alcohol and most nonpolar organic solvents and insoluble in water.[2] The available chemical and physical properties of Cetearyl Octanoate are listed in Table 1.

Reactivity

No specific information was available on the reactivity of this ingredient, but it can be expected to undergo chemical or enzymatic hydrolysis to 2-ethyl-hexanoic acid and the corresponding alcohols.

TABLE 1. CHEMICAL AND PHYSICAL PARAMETERS OF CETEARYL OCTANOATE.[a]

Solid point	*Sp. gr.*	*Refr. ind.*	*Ester value*	*Acid value*	*Iodine value*	*Saponification value*
−4.0 °C to 1.0 °C	0.852 to 0.857 20 °C	1.444 to 1.446 20 °C	135 to 160	1.0 maximum	0.0 to 2.0	135 to 160

[a]From Refs. 1, 2.

Transesterification and other typical ester reactions may also occur. All of the esters present are saturated compounds and would not be expected to autooxidize readily.

Analytical Methods

Positive identification can be made through close matching to standard IR spectra with no indication of foreign materials.[2]

Hashimoto et al.[6] describe a method for thin-layer chromatography applicable to the subject ingredient.

Impurities

The industry's purchasing specifications for Cetearyl Octanoate include the following maximum allowable concentrations of chemical impurities:[1]

Heavy Metal (as Pb) ..... 10 ppm maximum
Arsenic (as As) ..... 0.3 ppm maximum

USE

Purpose in Cosmetics

Cetearyl Octanoate is a synthetic mixture of fatty acid esters that resembles the preen gland secretion of aquatic birds; thus, it imparts water repelling characteristics to cosmetic formulations. It is also used as an agent that improves "spreadability" and as a "refatting material for dry skin conditions."[5]

TABLE 2. PRODUCT FORMULATION DATA.[a]

Cosmetic product type	*Concentration[b] (Percent)*	*No. of product formulations*
Cetearyl Octanoate		
Bath oils, tablets and salts	>1.0–5	1
Other bath preparations	>1.0–5	1
Eyeliner	>0.1–1	3
Eye shadow	>0.1–1	1
	≤0.1	7
Eye makeup remover	>5.0–10	1
Mascara	>0.1–1	15
	≤0.1	3
Other eye makeup preparations	>1.0–5	1
	>0.1–1	1

TABLE 2. (Continued).

Cosmetic product type	*Concentration*[b] *(Percent)*	*No. of product formulations*
Hair conditioners	>1.0–5	4
	>0.1–1	1
Hair sprays (aerosol fixatives)	>1.0–5	1
Rinses (noncoloring)	>1.0–5	3
	>0.1–1	1
Other hair preparations	≤0.1	1
Blushers (all types)	>5.0–10	1
	>1.0–5	9
Face powders	>0.1–1	12
Foundations	>1.0–5	2
Lipstick	>1.0–5	2
Makeup bases	>1.0–5	11
Other makeup preparations	>1.0–5	4
	>0.1–1	1
Douches	>5.0–10	1
Feminine hygiene deodorants	>0.1–1	1
Preshave lotions (all types)	>1.0–5	2
	≤0.1	1
Cleansing (cold creams, cleansing	>10–25	1
lotions, liquids, and pads)	>1.0–5	1
	>0.1–1	3
Face, body, and hand (excluding	>1.0–5	8
shaving) preparations	>0.1–5	1
Moisturizing	>5.0–10	3
	>1.0–5	11
	>0.1–1	2
Night	>5.0–10	1
	>1.0–5	4
Paste masks (mud packs)	>0.1–1	1
Other skin care preparations	>10–25	1
	>1.0–5	3
Suntan gels, creams, and liquids	>1.0–5	2
	≤0.1	1

[a]From Ref. 7.

[b]Preset concentration ranges in accordance with federal filing regulations [21 CFR 720.4(d)(1)].

Table 2 lists product types and the number of product formulations that contained Cetearyl Octanoate as of 1976.[7] Voluntary filing of such information by cosmetic manufacturers conforms to the prescribed format of preset concentration ranges and product types as described in 21 CFR part 720.[8] In 1976, Cetearyl Octanoate was reported as an ingredient in 135 cosmetic formulations; two products contained between 10% and 25% Cetearyl Octanoate, while all others used less than 10%.

Surfaces to which Commonly Applied

Products containing this ingredient are applied to all areas of the skin, hair, nails, and mucous membranes. They are most often applied to the face and around the eyes. These formulations may be applied several times a day and may remain in contact with the skin for variable periods of time after each application. Daily or occasional use may extend over many years (Table 2).

BIOLOGICAL PROPERTIES

Absorption, Metabolism, Storage, and Excretion

Although no specific information on Cetearyl Octanoate was available, comparison to similar long chain fatty acid esters suggests that it would be hydrolyzed in the gastrointestinal tract to 2-ethylhexanoic acid and the corresponding alcohols. These products, in turn, would enter their respective metabolic pathways.

Animal Toxicology

Acute Studies

Oral toxicity

In each of two studies,[9,10] young adult albino rats were fasted for 24 h and given a single administration of undiluted Cetearyl Octanoate by gavage. They were then allowed free access to food and water for 14 days. In the first study,[9] Cetearyl Octanoate was administered to four groups of 10 rats each in doses of 3.98, 5.01, 6.31, or 8.00 ml/kg. There were no deaths and no reported signs of toxicity. In the other study,[10] 10 rats received 5 ml/kg each. None died, but all showed signs of decreased activity, ataxia, and diarrhea. From these data, the acute oral LD50 for Cetearyl Octanoate is estimated to be greater than 8.0 ml/kg.

Acute oral toxicity tests were conducted on product formulations containing 2.5%[11] and 5.0%[12] Cetearyl Octanoate. The product containing 5.0% was diluted by 50% with volatile silicone, giving an effective concentration of 2.5% Cetearyl Octanoate. In each test, 15 ml/kg doses were administered to a group of 10 adult mice. None of the animals died.

Dermal toxicity

The acute dermal toxicity of Cetearyl Octanoate was studied on six rabbits.[9] The undiluted test material was applied to the intact and abraded clipped skin of the trunk and held in contact for 24 h. The animals were divided into four groups:

Group I—2 control rabbits received no test material
Group II—2 rabbits received 3.9 ml/kg
Group III—2 rabbits received 6.0 ml/kg
Group IV—2 rabbits received 9.4 ml/kg

After 24 h, the exposed areas were scored on a Draize scale of 0–4 for erythema and edema. The animals were further observed for two weeks. Initial gradings ranged from 0 to 1.5, and it was concluded that the material produced only a mild irritation which disappeared in all dose levels by Day 10. There were no deaths and no changes in urine, blood morphology, or gross appearance.

An aerosol spray product formulation containing 25–30% Cetearyl Octanoate in its concentrate was tested for acute dermal toxicity on a group of five male and five female albino rabbits.[13] Five animals received epidermal abrasions, and five retained intact skin. The product was sprayed on the test site for 10 seconds (1.5–2.6 g/kg), and the site was covered with an occlusive bandage for 24 h. There were no detectable skin reactions, toxic and/or pharmacologic effects, or mortality in any of the animals.

Primary skin irritation

The primary skin irritancy potential of Cetearyl Octanoate was tested in two studies by a Draize single insult patch test technique. In each study, 1.5 ml samples of undiluted Cetearyl Octanoate were applied to the clipped intact and abraded skin of six albino rabbits and occluded for 24 h. The patch sites were evaluated according to the Draize scale following patch removal and again at 72 h. The Primary Irritation Indices in the two tests were 0.0[9] and 0.17,[14] indicating Cetearyl Octanoate to be a nonirritant.

Draize primary skin irritation tests were performed on product formulations containing 2.5%[15] and 5.0%[16] Cetearyl Octanoate. The product containing 5.0% was diluted by 50% with volatile

silicone, giving an effective concentration of 2.5% Cetearyl Octanoate. Each study used 0.5 ml doses applied to the abraded and intact skin of three albino rabbits. The formulation containing 2.5% Cetearyl Octanoate produced slight erythema with a Primary Irritation Index of 0.5, whereas the product containing 5.0%, diluted with silicone, produced no signs of irritation.

Eye irritation

Modifications of the Draize rabbit eye irritation procedure were used in two separate studies. In each, undiluted Cetearyl Octanoate was instilled in one eye of each rabbit; the untreated eye served as control. Grading according to the Draize scale for ocular lesions was conducted at 24, 48, and 72 h and again at seven days. In the first study,[9] three groups of three animals each received 0.1 ml samples of the undiluted test material:

Group I—3 animals' treated eyes remained unwashed
Group II—3 animals' treated eyes were washed with 20 ml lukewarm water 2 sec after instillation
Group III—3 animals' treated eyes were washed with 20 ml lukewarm water 4 sec after instillation

There was no eye irritation in Group I, but the treated eyes in Groups II and III showed mild irritation. The total Ocular Irritation Index (OII) for all nine animals was 0.78 at 24 h and 0.0 thereafter. In the other study,[17] the test material was administered to six animals as a two-second spray held six inches from the rabbit's eye. The OII was 0.0; no ocular reactions were observed. Since the maximum total score on the Draize scale is 110, these studies indicate Cetearyl Octanoate to be nonirritating to the rabbit eye.

The Draize eye irritation test or a modification of it was performed on three product formulations containing 2.5%[18] 5.0%,[19] and 25–30%[20,21] Cetearyl Octanoate. The product containing 5.0% was diluted by 50% with volatile silicone, giving an effective concentration of 2.5% Cetearyl Octanoate. No significant ocular irritation was produced by any of the formulations.

Mucous membrane irritation

The potential for mucous membrane irritation by a feminine deodorant aerosol product, the concentrate of which contained 25–30% Cetearyl Octanoate, was tested in two studies with hamsters and dogs. In the first study,[22] a two-second spray was administered from a distance of six inches directly on the everted left cheek pouch of each of four Golden Syrian hamsters. The untreated right cheek pouch served as a control. The formulation was administered once daily for three consecutive days under Diabutal anesthesia. No irritation was seen in any of the pouches. In the other study,[23] the aerosol formulation was administered as a two-second spray into the vaginal vaults of two dogs for four consecutive days. The vaginal mucosa was biopsied and examined for gross signs of irritation four hours after the fourth treatment. No signs of irritation were observed, and the vaginal tissue appeared grossly normal.

Phototoxicity

A guinea pig phototoxicity test was performed on a moisturizer lotion containing 3.2% Cetearyl Octanoate.[24] Each of three animals received 0.1 ml of the moisturizer and 0.05 ml of Oxsoralen, a positive control, on different test sites. The animals were exposed to 60 minutes of UV range A (320–400 nm) light 15–20 min after application, and irradiated and nonirradiated test sites were evaluated for erythema. The product formulation produced no signs of phototoxicity.

Inhalation

Ten adult rats were placed in a 100 l inhalation chamber and exposed for 1 h to a concentration of 30 mg/l of an aerosol formulation containing 1.9–2.2% Cetearyl Octanoate.[25] The rats were removed from the chamber and examined for signs of toxicity immediately and daily thereafter for 14 days. No toxic signs were seen at any time during the test. The incidence of gross lesions seen at autopsy was comparable in treated and control animals.

Subchronic Studies

Skin sensitization

The sensitization potential of Cetearyl Octanoate was tested with the Landsteiner and Jacobs guinea pig sensitization technique.[9] The backs and flanks of nine white male guinea pigs were clipped free of hair, and a 0.1% solution of Cetearyl Octanoate in Olive Oil USP was injected in-

tracutaneously three times weekly for a total of 10 injections. The first injection consisted of 0.05 ml, whereas the remaining nine were 0.1 ml each. A challenge injection of 0.05 ml of freshly prepared solution was administered just below the sensitization area two weeks after the tenth sensitization injection. The challenge site was evaluated 24 h later and compared with similar readings taken after the earlier injections. There were no signs of sensitization.

A moisturizer lotion containing 3.2% Cetearyl Octanoate was tested according to the Landsteiner and Jacobs guinea pig sensitization technique.[26] Groups of eight animals received topical applications of the product formulation, a 0.9 percent saline solution (negative control), or 0.1% dinitrochlorobenzene in acetone (positive control). The moisturizer lotion produced no evidence of skin sensitization.

Dermal toxicity

Cetearyl Octanoate was applied daily in doses of 1.0, 2.0, or 4.0 ml/kg by gentle inunction to the clipped intact and abraded skin of albino rabbits.[9] Two animals were used at each dose level and two served as controls. Applications were made five days a week for a total of 20 applications in four weeks. Observations were made daily on body weight, food consumption, and behavior. Urine and blood samples were analyzed at the beginning and end of the study. Cetearyl Octanoate was only very mildly irritating to the skin. The urine and blood data showed no significant deviations from normal, and no other toxic effects were observed.

A dermal toxicity study was conducted in which 0.25, 0.5, 1.0, or 2.0 ml/kg of undiluted Cetearyl Octanoate was applied by gentle inunction to the skin of rabbits daily for 90 days.[9] Three animals were used at each dose level; one received epidermal abrasions. Autopsies of all animals were performed at the end of the test, and the skin, lungs, spleen, liver, and kidneys were examined for histopathologic changes. Urine and growth response were normal. Hematological findings were normal except in one animal which, upon autopsy, showed a severe heart condition unrelated to the experimental manipulations. There was no relation between the dose level and observed histopathological abnormalities of internal organs. The skin showed changes in the epidermis indicative of mild irritation, but there were no changes in the dermis.

Clinical Assessment of Safety

Skin Irritation

A single insult patch test was performed on 100 individuals, 69 women and 31 men, ranging in age from 14 to 72.[9] All but two of the subjects were hospital patients suffering from some kind of skin disease, and 92 of the tested individuals had a history of allergy. Approximately 0.5 ml of 100% Cetearyl Octanoate was applied under a patch and left in place for 24 h. Two subjects showed a positive reaction at 24 h; one reaction persisted and one disappeared by 48 h. Two other subjects developed a reaction by 48 h, one moderate and one very mild. Thus, four of the 100 test subjects showed a slight to moderate skin reaction to Cetearyl Octanoate in a 24-hour patch test.

A modified Lanman 21-day cumulative skin irritancy patch test procedure was used to evaluate the irritancy potential of a hair preparation containing 0.40% Cetearyl Octanoate.[27] The test material was applied under occlusive patches on the back for 21 consecutive days, as were both positive and negative control substances. The 13 panelists produced a cumulative score which elicited the classification of "essentially nonirritating."

Skin Sensitization

The Draize-Shelanski repeated insult patch test procedure or a modification of it was performed on six cosmetic product formulations containing 0.2-30% Cetearyl Octanoate. The test material was applied three times a week for a total of ten induction applications. After a two-week rest period, a challenge patch was applied and left on for 24, 48, or 72 h. The results and other details of the studies are summarized in Table 3; no reactions indicative of skin irritation or sensitization were observed in a total of 644 subjects.

A maximization test was also used to test the sensitization potential of a product formulation containing Cetearyl Octanoate.[28] One forearm of each of 25 adult subjects was pretreated with 1%

TABLE 3. HUMAN REPEAT INSULT PATCH TESTS FOR SKIN IRRITATION AND SENSITIZATION.

Product	*Conc. of Cetearyl Octanoate (percent)*	*No. of subjects*[a]	*Induction exposure period/Patch (h)*	*No. of subjects reacting during induction phase*	*Challenge exposure period (h)*	*No. of reactions at Challenge*	*Ref.*
Halston Eye Cream	0.2	56	24	0	48	0	30
Halston Cleaner	1	50	24	0	48	0	31
Suntan Lotion	2.5	19	24	0	24	0	29
Moisturizing Lotion	3.2	204	48	0	72	0	32
Bath Gel	5	111	48	4 with doubtful reactions	48	0	33
Feminine Deodorant Aerosol	25–30	204	48	0	48	0	34

[a]Subjects completing study.

sodium lauryl sulfate. The test material, which contained 0.40% Cetearyl Octanoate, was then applied under an occlusive dressing for five 48-hour exposures. Following a 10-day rest, the opposite upper arm was pretreated with 10% sodium lauryl sulfate, and a challenge patch of the test material was applied for another 48-hour exposure under occlusion. No instances of contact-sensitization from this material were detected in the maximization test.

Photocontact Allergenicity

A photocontact allergenicity test was conducted on a suntan lotion containing 2.5% Cetearyl Octanoate.[29] Approximately 0.2 ml of the product was applied under an occlusive patch on each forearm of 27 adults. After 24 h, one forearm of each subject was exposed for 15 min to nonerythrogenic ultraviolet radiation at a distance of 10–12 cm from the light source for a total light dosage of 4,400 $\mu W/cm^2$. The light source produced UV-A radiation with a peak at 360 nm. The other arm served as a nonirradiated control. After skin reactions were scored, the test sites were covered with untreated patches to prevent inadvertent exposure to sunlight. This procedure was repeated three times a week until a total of 10 induction treatments had been made. After a 10–14 day rest period, the subjects were challenged with the test material under patches which were applied to the original contact site and a fresh, adjacent site. The patches were removed after 24 h, and the test sites were irradiated and scored as before. Additional readings were taken at 48 and 72 h after application. The suntan lotion produced slight irritation in four subjects. One of these subjects exhibited a slight delayed reaction after the sixth exposure of the induction phase at both control and irradiated sites; however, no further reactions were observed at either site. Two subjects showed slight reactions, one after the ninth and one after the 10th induction exposure, but neither subject reacted to the challenge. The fourth subject reacted with erythema after the eighth exposure, but the reaction dissipated after the site was irradiated. This subject also showed a slight erythema after challenge. The investigator concluded that none of the reactions was significant enough to show evidence of photoallergy.

Phototoxicity

A suntan lotion containing 2.5% Cetearyl Octanoate was tested for phototoxicity on 10 subjects who ranged in age from 22 to 49 years.[29] The inner aspects of the forearms were scrubbed with alcohol and tape-stripped 6–10 times to remove several layers of cornified epithelium. About 0.2 g of the product was applied under an occlusive patch to each test site and left in place for 24 h. One forearm of each subject was then exposed to UV light for 15 min at a distance of 10–12 cm from the light source, for a total UV light dosage of 4,400 $\mu W/cm^2$. No reactions occurred, and it was concluded that the product was not phototoxic.

The phototoxicity study on a product containing 2.5% Cetearyl Octanoate is not sufficient to assess the ingredient's potential for phototoxicity when it is present at the greater concentrations (up to 25%) found in some cosmetic products. Nevertheless, clinical experience indicates that it is unlikely Cetearyl Octanoate would produce any such phototoxic reactions.

SUMMARY

Cetearyl Octanoate is the esterification product of 2-ethylhexanoic acid and cetearyl alcohol. It is used in a wide variety of cosmetic products which may be applied to all areas of the body.

The acute oral LD50 for Cetearyl Octanoate is estimated from studies with rats to be greater than 8.0 ml/kg. The ingredient produced no significant skin or eye irritation in Draize rabbit irritation tests, and it was not toxic in acute and subchronic dermal toxicity tests with rabbits. The ingredient produced no evidence of skin sensitization in a guinea pig sensitization test.

Product formulations containing between 1.9% and 30% Cetearyl Octanoate were also tested in a variety of animal studies. They produced no signs of acute oral toxicity (Cetearyl Octanoate at 2.5%) acute dermal toxicity (25–30%), skin irritation (2.5%), eye irritation (2.5–30%), mucous membrane irritation (25–30%), skin sensitization (3.2%), inhalation toxicity (1.9–2.2%), or phototoxicity (3.2%).

In clinical studies, four of 100 subjects showed slight to moderate irritation after a 24-hour skin

patch with undiluted Cetearyl Octanoate, while a product containing 0.4% Cetearyl Octanoate was classified as "essentially nonirritating" in a 21-day cumulative skin irritation test. Product formulations containing between 0.2% and 30% Cetearyl Octanoate were tested on a total of 644 subjects with no signs of skin sensitization. Photocontact allergenicity and phototoxicity studies showed no evidence of photoreactivity for a product containing 2.5% Cetearyl Octanoate.

CONCLUSION

From the available information, the Panel concludes that Cetearyl Octanoate is safe as a cosmetic ingredient in the present practices of use.

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