Safety Assessment of Stearalkonium Chloride as Used in Cosmetics

Status:	Re-Review for Panel Consideration
Release Date:	February 10, 2023
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The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; David E. Cohen, M.D.; Curtis D. Klaassen, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Thomas J. Slaga, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D. This safety assessment was prepared by Priya Cherian, M.S., Senior Scientific Analyst/Writer, CIR.

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Cosmetic Ingredient Review

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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Priya Cherian, M.S., Senior Scientific Analyst/Writer, CIR
Date: February 10, 2023
Subject: Re-Review of the Safety Assessment of Stearalkonium Chloride

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published a review of the safety of Stearalkonium Chloride in 1982 (identified as *originalreport_StearalkoniumChloride_032023* in the pdf), with the conclusion that Stearalkonium Chloride is "safe when incorporated in cosmetic products in concentrations similar to those presently marketed." The Panel previously considered a re-review of this report and re-affirmed the 1982 conclusion, as published in 2003 (*rereview2003_StearalkoniumChloride_032023*).

Because it has been at least 15 years since the previous re-review was published, in accord with Cosmetic Ingredient Review (CIR) Procedures, the Panel should consider whether the safety assessment of Stearalkonium Chloride should be re-opened. An extensive search of the world's literature was performed for studies dated 1999 forward. An historical overview, comparison of original and new use data, the search strategy used, and a synopsis of notable new data are enclosed herein (*newdata_StearalkoniumChloride_032023)*.

New studies were found for several toxicological endpoints (ADME, acute toxicity, DART, genotoxicity, dermal irritation, and ocular irritation). These studies were found in an ECHA dossier on Stearalkonium Chloride that referenced read-across test substances for much of the data. These data have been included in the new data document.

It should be noted that according to European Union (EU), Stearalkonium Chloride is used in rinse-off hair products, and ready-to-use preparations should not contain more than 0.3% (as benzalkonium chloride). Final product concentrations of benzalkonium chloride, bromide, and saccharinate with an alkyl chain of C_{14} or less must not exceed 0.1% (as benzalkonium chloride). EU restrictions also state that when using this ingredient for purposes other than inhibiting the development of microorganisms, the purpose must be apparent from the presentation of the product, and concentrations must not exceed 0.1% (as benzalkonium chloride, when used as a preservative). In addition, according to the United States Food and Drug Administration, Stearalkonium Chloride is safe for use as a food additive, anti-microbial agent, adhesive, and slimicide (under certain restrictions).

Also included for your review is a table of current and historical use data (*usetable_StearalkoniumChloride_032023).* (As per the Panel's request at the December 2022 meeting, an updated use table format has been implemented. The frequency and concentration of use is presented both cumulatively by likely duration and exposure and individually by product category.) The frequency and concentration of use of Stearalkonium Chloride has decreased since this ingredient was last considered for re-review. According to 2022 frequency of use and concentration of use data, Stearalkonium Chloride is used in 88 formulations at up to 3.8%; in 2001, it was reported to be used in 151 formulations at up to 7%.

If upon review of the new studies and updated use data the Panel determines that a re-review is warranted, a Draft Amended Report will be presented at an upcoming meeting.

Re-Review – Stearalkonium Chloride - History and New Data

(Priya Cherian – March 2023 meeting)

Ingredient (1)	Citation	Conclusion	Use - New Data	Results	Use - Existing Data	Results	Notes
Stearalkonium Chloride	JACT 1(2):57-69, 1982 IJT 22(Suppl. 1):1-35, 2003	safe as used* reaffirmed	frequency of use (2022) conc of use (2022)	88 ≤ 3.8%	frequency of use (2001) conc of use (2001)	151 ≤ 7%	Decrease in frequency and concentration of use

*According to the 1982 published report, Stearalkonium Chloride was considered safe when incorporated in cosmetic products in concentrations similar to those presently marketed

NOTABLE NEW DATA			
Publication	**Study Type**	**Results – Brief Overview**	**Different from Existing Data?**
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.simple *Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (Text with EEA relevance) (legislation.gov.uk)* *Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (Text with EEA relevance) (legislation.gov.uk)*	European Union Legislation – CosIng	Stearalkonium Chloride is listed in annex III and V of Regulation (EC) No 1223/2009; for purposes other than inhibiting the development of microorganisms in the product, this purpose must be apparent from the presentation of the product; maximum concentration when used as a preservative should not exceed 0.1% (as benzalkonium chloride)	EU restrictions not reported in previous report
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.simple *Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (Text with EEA relevance) (legislation.gov.uk)*	European Union Legislation - CosIng	Stearalkonium Chloride is listed in annex III and V of Regulation (EC) No 1223/2009; this ingredient is used in rinse-off hair products; the maximum concentration in ready-to-use preparations should not contain more than 3% (as benzalkonium chloride); in final products, concentrations of benzalkonium chloride, bromide, and saccharinate with an alkyl chain of C_{14} or less must not exceed 0.1% (as benzalkonium chloride) contact with eyes should be avoided	EU restrictions not reported in previous report
https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm	Non-Cosmetic Use	Stearalkonium Chloride is used as an inactive ingredient at 3.15% in a topical lotion (drug product)	Not included in previous report
21CFR172.165 *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.165*	Non-Cosmetic Use	Stearalkonium Chloride is safe for use as a food additive with the following specifications: • pH (5% active solution): 7.0 – 8.0 • total amine: maximum 1% as combined free amines and amine hydrochlorides • the additive is used as an antimicrobial agent in raw sugar cane juice • the additive is applied to the sugar juice at a quantity of 0.25 - 1 ppm	Not included in original report

NOTABLE NEW DATA			
Publication	**Study Type**	**Results – Brief Overview**	**Different from Existing Data?**
21CFR173.320 *eCFR :: 21 CFR 173.320 -- Chemicals for controlling microorganisms in cane-sugar and beet-sugar mills.*	Non-Cosmetic Use	Stearalkonium Chloride may be safely used as an agent to control microorganisms in cane-sugar and beet-sugar mills when used in amounts of no more than 0.05 ± 0.005 ppm	Not included in original report
21CFR175.105 *eCFR :: 21 CFR 175.105 -- Adhesives.*	Non-Cosmetic Use	Stearalkonium Chloride may be safely used as an adhesive intended for use in packaging, transporting, or holding food under several specifications	Not included in original report
21CFR176.300 *eCFR :: 21 CFR 176.300 -- Slimicides.*	Non-Cosmetic Use	Stearalkonium Chloride may be safely used as a slimicide under several specifications	Not included in original report
https://echa.europa.eu/da/registration-dossier/-/registered-dossier/24960/7/9/2	ADME - Dermal	OECD TG 417; test substance: radioactive quaternary ammonium compounds, benzyl C12-C16 (even numbered)-alkyldimethyl chlorides* (0.1 and 1%) and water (1.5 and 15 mg/kw bw); test substance purity: 49.9%; Sprague-Dawley rats (64/sex/group); dermal application of test substance; exposure area of 25-30 cm^2; 6 h exposure time; evaluations at time intervals up to 72 h for pharmacokinetic data and up to 168 h for urine and feces data; the maximum systemic absorption (feces, urine, carcass, and skin site) was 50 and 50.1% for males and females, respectively; test substance uniformly distributed in stratum corneum; mean plasma and blood levels for both sexes in the 1.5 mg/kg bw group remained below quantifiable limits at all time points except for the 7 and 8 h time point for blood (levels for males/females of 3.52/4.40 and 2.67/3.26 ng-eq/g, respectively). For the 15 mg/kg bw dose group only the 8 (levels of 70.2/68.6 ng-eq/g for males/females) and 24 h (levels of 62.3/55.0 ng-eq/g for males/females) time-points resulted in values above the quantifiable limits.	Dermal ADME data not included in previous report

NOTABLE NEW DATA			
Publication	**Study Type**	**Results – Brief Overview**	**Different from Existing Data?**
https://echa.europa.eu/da/registration-dossier/-/registered-dossier/24960/7/9/2	ADME – Oral	OECD TG 417; test substance: radioactive quaternary ammonium compounds, benzyl C12-C16 (even numbered)-alkyldimethyl chlorides* and water (50 and 200 mg/kg bw; concentration of test substance not stated); test substance purity: 49.9%; Sprague-Dawley rats (64/sex/group); gavage administration; evaluations at time intervals up to 96 h for pharmacokinetic data and up to 168 h for urine and feces data; elimination was quick, with 70-80% excreted within the first 24 h; no radioactivity was left in the carcass; mean plasma and blood levels for males and females remained below quantifiable limits at all time points except in the 50 mg/kg dose group for 0.5 to 2 h time points for plasma (161 and 251 ng -eq/g for males at 1 and 2 h respectively, and 109 ng-eq/g at 0.5 h, 212 ng-eq/g at 1h and 192 ng-eq/g at 2 h for females), and in blood at only the 1 h time point in females (173 ng-eq/g); at the 50 mg/kg bw dose level, mean radioactivity levels were below quantifiable limits in all tissues/ organs except for intestines (approximately 23% in males and females) and liver (0.087% in males and 0.039% in females) at the 24 h time point – levels were all non-quantifiable by 168 h; at the 200 mg/kg bw dose level radioactivity levels were above quantifiable levels in approximately half the tissues and organs evaluated at 24 h, with particularly high levels in the intestines (62.2% in males and 71.5% in females) – all levels were non-quantifiable by 168 h	No
https://echa.europa.eu/da/registration-dossier/-/registered-dossier/24960/7/9/2	Acute Toxicity – Oral	OECD TG: 401; test substance: quaternary ammonium compounds, benzyl C12-C16 (even numbered)-alkyldimethyl chlorides* and water; test substance purity: 50%; undiluted test substance given via gavage to Sprague-Dawley rats (10/sex/dose) in doses of 500, 795, 1260, and 2000 mg/kg bw; LD_{50} = 795 mg/kg bw (equivalent to 397.5 mg actually ingested/kg bw)	No
https://echa.europa.eu/da/registration-dossier/-/registered-dossier/24960/7/9/2	Subchronic Toxicity – Oral	OECD TG 409; test substance: quaternary ammonium compounds, benzyl C12-C16 (even numbered)-alkyldimethyl chlorides* and water (50% purity); Beagle dogs (4/sex/group); animals given test substance in died at concentrations of 0, 500, 1500, and 3000 ppm); no treatment-related toxicologically significant effects were observed at any tested concentration	No subchronic oral toxicity data was provided in the original report

NOTABLE NEW DATA			
Publication	**Study Type**	**Results – Brief Overview**	**Different from Existing Data?**
https://echa.europa.eu/da/registration-dossier/-/registered-dossier/24960/7/9/2	DART – oral	OECD TG 416; test substance: quaternary ammonium compounds, benzyl C12-C16 (even numbered)-alkyldimethyl chlorides* and water; Sprague-Dawley rats (25/sex/group) given test substance (49.9% purity) at concentrations of 0, 500, 2000, and 4000 ppm in diet over a 10 wk period prior to mating, 2 wk during mating, and until after weaning of pups; from every litter, F1 animals treated similarly as parents, and F2 animals evaluated; systemic toxicity NOAEL for P1 generation: 500 ppm (due to lowered body weight gain, food consumption, lower liver weights; reproductive toxicity for P1 generation: 2000 ppm; NOAEL for reproductive toxicity for F1: 2000 ppm (due to lower spleen weights at highest concentration); NOAEL for reproductive toxicity for F2: 2000 ppm (due to reduced litter size at highest concentration)	No two-generation reproductive toxicity assays were provided in the original report – however, a teratogenicity assay performed using myristalkonium chloride (read-across ingredient; gavage administration; up to 50 mg/kg; given to pregnant rats on days 6-15 of gestation) did not induce any indication of teratogenicity
https://echa.europa.eu/da/registration-dossier/-/registered-dossier/24960/7/9/2	Genotoxicity- In Vitro	OECD TG 471; Ames assay; Stearalkonium Chloride (96.2% active; up to 5000 µg/plate); evaluated in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA 1537, and *Escherichia coli* WP2uvrA; tested with and without metabolic activation; non-mutagenic	Genotoxicity data were not provided in original report
https://echa.europa.eu/da/registration-dossier/-/registered-dossier/24960/7/9/2	Dermal Irritation – In Vitro	OECD TG 439; reconstructed human epidermis in vitro assay; undiluted Stearalkonium Chloride (16 ± 2 mg) tested on reconstructed human epidermis in triplicate; 42 min incubation; non-irritating	In vitro dermal irritation assays were not provided in original report – human studies in original report did not report irritation; however, irritation was noted in studies performed in animals
https://echa.europa.eu/da/registration-dossier/-/registered-dossier/24960/7/9/2	Dermal Irritation – animal	Test substance: quaternary ammonium compounds, benzyl C12-C16 (even numbered)-alkyldimethyl chlorides* and water (96.2% actives); modified Draize assay; tested at concentration of 0.1% for intradermal induction and challenge; non-sensitizing	Animal dermal sensitization assays were not provided in original report – human studies in original report did not report sensitization

NOTABLE NEW DATA			
Publication	**Study Type**	**Results – Brief Overview**	**Different from Existing Data?**
https://echa.europa.eu/da/registration-dossier/-/registered-dossier/24960/7/9/2	Ocular Irritation – In Vitro	OECD 492; EpiOcular™ assay; undiluted Stearalkonium Chloride (96.2% active; 50 mg) applied to duplicate tissues; 6-h exposure period followed by incubation with MTT; viability of tissues assessed and compared to negative control (water) and positive control (methyl acetate); percentage viability was 5.7% for the test substance, 17.1 for the positive control, and 100% for the negative control, suggesting ocular irritation	No

ADME = absorption, distribution, metabolism, and excretion; CFR = Code of Federal Regulations; DART = developmental and reproductive toxicity; EU = European Union; LD_{50} = median lethal dose; MTT = 3-(4,5-Dimethylthiazol-2-yl)-2,5-Diphenyltetrazolium Bromide; OECD TG = Organisation for Economic Co-operation and Development Test Guidelines

*read-across data (test substances chemically similar to Stearalkonium Chloride)

Search (from 1999)
PubMed
(((“stearalkonium chloride”) OR (122-19-0 [CAS No.])) AND (("1999"[Date - Publication] : "3000"[Date - Publication])) – 4 hits; 0 useful

Table 1. 2022 and historical frequency and concentration of use according to likely duration and exposure and by product category

	# of Uses		*Max Conc of Use (%)*	
	2022[1]	**2001[2]**	**2022[3]**	**2001[2]**
	Stearalkonium Chloride			
Totals	**88**	**151**	**0.0055 – 3.8**	**0.3 - 7**
summarized by likely duration and exposure*				
Duration of Use				
Leave-On	*22*	*25*	*0.0055 – 3.8*	*0.3 – 3*
Rinse-Off	*66*	*121*	*0.25 – 3*	*0.4 – 7*
Diluted for (Bath) Use	*NR*	*5*	*NR*	*NR*
Exposure Type*				
Eye Area	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR
Incidental Inhalation-Spray	1; 12[a]; 2[b]	3; 15[a]; 2[b]	0.0055; 0.09 – 3.8[a]	0.3[a]
Incidental Inhalation-Powder	2[b]	2[b]	NR	NR
Dermal Contact	3	10	NR	0.3
Deodorant (underarm)	NR	NR	NR	NR
Hair - Non-Coloring	79	140	0.0055 – 3.8	0.7 - 7
Hair-Coloring	6	NR	0.38 – 1.3	0.4 – 2
Nail	NR	1	NR	NR
Mucous Membrane	NR	6	NR	NR
Baby Products	NR	NR	NR	NR
as reported by product category				
Bath Preparations (diluted for use)				
Bubble Baths	NR	5	NR	NR
Hair Preparations (non-coloring)				
Hair Conditioner	55	107	0.25 - 3	0.7 – 7
Hair Spray (aerosol fixatives)	1	3	0.0055	NR
Hair Straighteners	1	NR	NR	NR
Permanent Waves	NR	2	NR	NR
Rinses (non-coloring)	2	5	NR	3
Shampoos (non-coloring)	2	4	1.5	2
Tonics, Dressings, and Other Hair Grooming Aids	12	14	0.09 – 3.8	2 – 3
Wave Sets	NR	2	NR	NR
Other Hair Preparations	6	3	NR	2
Hair Coloring Preparations				
Hair Dyes and Colors (all types requiring caution statements and patch tests)	1	NR	NR	0.5 – 2
Hair Rinses (coloring)	NR	NR	1.3	NR
Hair Bleaches	NR	NR	0.38	0.4
Other Hair Coloring Preparation	1	NR	NR	NR
Manicuring Preparations (Nail)				
Nail Polish and Enamel	NR	1	NR	NR
Personal Cleanliness Products				
Other Personal Cleanliness Products	NR	1	NR	NR
Skin Care Preparations				
Body and Hand (exc shave)	2	2	NR	NR
Moisturizing	NR	1	NR	0.3
Other Skin Care Preparations	1	NR	NR	NR

NR – not reported

*likely duration and exposure is derived based on product category (see Use Categorization https://www.cir-safety.org/cir-findings)

**Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.

[a] It is possible these products are sprays, but it is not specified whether the reported uses are sprays.

[b] Not specified whether a spray or a powder, but it is possible the use can be as a spray or a powder, therefore the information is captured in both categories

[c] It is possible these products are powders, but it is not specified whether the reported uses are powders.

REFERENCES

1. US Food and Drug Administration (FDA) Center for Food Safety & Applied Nutrition (CFSAN). 2022. Voluntary Cosmetic Registration Program - Frequency of Use of Cosmetic Ingredients. (Obtained under the Freedom of Information Act from CFSAN; requested as "Frequency of Use Data" January 4, 2022; received January 11, 2022). College Park, MD.

2. Andersen FA (ed). Annual review of cosmetic ingredient safety assessments - 2001/2002. *IJT.* 2003;22:1-35.

3. Personal Care Products Council. 2022. Concentration of use by FDA product category: Stearalkonium Chloride. (Unpublished data submitted by Personal Care Products Council on October 31, 2022.)

4

Final Report on the Safety Assessment of Stearalkonium Chloride

Stearalkonium Chloride is a cationic quaternary ammonium salt used in cosmetic products at concentrations of ≤0.1 to 5%. It is used in cosmetics predominantly for its surfactant and antimicrobial properties.

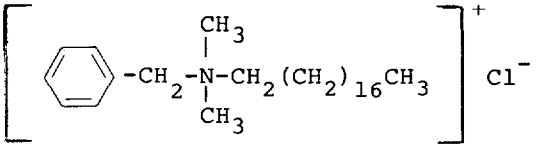
Studies have failed to establish with certainty the oral LD50 in rats of Stearalkonium Chloride, the value falling between 0.5 and 1.25 g/kg. In mice, an LD50 value of 0.760–0.113 g/kg was reported in a seven-day oral study. Single application dermal studies with concentrations of up to 25% have shown Stearalkonium Chloride to produce minor irritation in rabbits. Acute eye studies in rabbits have shown a 25% solution of the material to be a severe irritant. Concentrations of 1.25% and less are slightly and transiently irritating to the rabbit eye.

A repeated insult patch test with a 1% aqueous solution of Stearalkonium Chloride on 50 subjects showed the material to be neither a primary irritant nor a sensitizer. A single 48-hour patch test with challenge two weeks later indicated that 20% Stearalkonium Chloride is not a sensitizer.

On the basis of the evidence at hand, it is concluded that Stearalkonium Chloride is safe when incorporated in cosmetic products in concentrations similar to those presently marketed.

CHEMICAL PROPERTIES

Stearalkonium Chloride is a quaternary ammonium salt. The compound consists of an aliphatic hydrophobic portion and a nitrogenous hydrophilic portion. Because of this amphoteric property and also because of the fact the compound carries a positive charge upon ionization, Stearalkonium Chloride is classified as a cationic surfactant. It has the following structural formula:[1,2]



The respective structures of Cetalkonium and Myristalkonium Chlorides, two compounds closely related to Stearalkonium Chloride, are the same as above, except that the stearyl ($-CH_2(CH_2)_{16}CH_3$) moiety is replaced by cetyl ($-CH_2(CH_2)_{14}CH_3$) or myristyl ($-CH_2(CH_2)_{12}CH_3$) moieties. The safety of Cetalkonium and Myristalkonium Chlorides is not under review in this report. Information and data pertaining to these two compounds have been included to permit a more complete appraisal of the safety of Stearalkonium Chloride. The three alkonium compounds are prepared by the quaternization of the appropriate alkyldimethylamine (stearyl, cetyl, or myristyl) with benzyl chloride. Each is a free flowing powder normally sold as a dispersion in isopropyl alcohol and/or water.[3]

Physical Properties

The melting points of a homologous series of this class of compounds decrease sharply from chain lengths of C_8 to C_{11} and gradually increase with longer alkyl groups. Those with chain lengths of C_8 to C_{13} are soluble in water. The odd-numbered compounds are more soluble in 95% ethanol than even-numbered ones.[3] The pH ranges for 1% and 10% aqueous solutions of Stearalkonium Chloride are 3.5–6.5 and 3–4, respectively.[4,5] The ability to lower the surface tension of water increases with increasing chain length (C_8 to C_{19}) until a minimum of 42–43 dynes/cm is approached.[3]

Aqueous solutions of Cetalkonium Chloride and other quaternary ammonium compounds at concentrations above their critical micelle concentration (CMC) were studied as a function of monovalent electyrolyte concentration and temperature. At a given temperature, there is a critical electrolyte concentration above which the material separates into two phases; the top layer is virtually free of the quaternary ammonium salt, and the bottom layer shows the characteristics of an oil. The volume of the bottom layer decreases with increasing electrolyte concentration. Before separation, turbidity and dissymmetry of light scattering rise sharply with increasing eletrolyte concentration. The phenomenon of two-phase formation in Cetalkonium Chloride and other cationic soap systems shows a pronounced specificity to the anions of the added electrolyte. Small temperature changes produced marked changes in the volume of each layer in the two-phase systems.[6]

The electrical conductance of long-chain alkyldimethylbenzylammonium chlorides (C_{10} to C_{16}) has been studied through the use of a Wheatstone Bridge with an oscilloscope detector. The resulting conductance curves were used to determine C values (Table 1). Calculated values indicate that an increase in chain length by one methylene group changes the free enthalpy of micellization by a constant value.[7]

In a series of studies in which viscosity and conductance measurements were

TABLE 1. Critical Micelle Concentration Values.[a]

Ingredient	*CMC mole/dm³*
Stearalkonium Chloride	Not available
Cetalkonium Chloride	2.9×10^{-4}
Myristalkonium Chloride	1.9×10^{-3}

[a]Data from Ref. 8.

made in molten pyridinium chloride, Bloom and Peinsborough[8,9] determined the CMC of Cetalkonium Chloride to be 0.06–0.07 *M* at 155 °C. Another method has been described for determining micellar charge using the osmotic response of permeable, charged membranes.[10] With increased alkyl chain-length, alkylbenzylammonium chlorides exhibit increasing ability to lower surface tension in the presence of excess electrolyte; this increase adheres closely to Traube's rule. (The surface tension of dilute solutions of certain organic compounds decreases with the increase of the carbon chain length within homologous series.) There is significant deviation in these materials' ability to lower surface tension in the absence of electrolyte.[11]

Reactivity

The cationic charge possessed by these materials enables them to react with the anionic charge of other substances. This permits these compounds to precipitate carrageenan and other sulfated hydro-colloids at critical temperatures and pH values. These materials form water insoluble precipitates when combined with tannic, gallic, and salicylic acids. Their property of lowering surface tension makes possible many chemical reactions, including the basic hydrolysis of carboxylic acid esters of polyvinyl alcohol.[12-14]

It can be expected that in the presence of nitrites, nitrogen oxides, or other nitrosating agents, alkylbenzyldimethylammonium chlorides will give rise to traces of N-nitrosamines. Furthermore, the significant impurities, alkyldimethylamines (Table 2), are easily nitrosated to N-nitrosamines.

Analytical Methods

Quantitative determinations of all cationic surfactants can be accomplished by a two-phase titration with thymolphthalein, eosin, or methylene blue, as indicated. They can also be identified by paper chromatography.[15,16]

Cationic surfactants react with thymolsulfonaphthalein dyes to form large cation–anion complexes. Following a series of extractions, photometric determination of the cationic surfactant complex with thymolsulfonaphthalein is made by the colorimetry at 555 nm.[17]

Spectrophotometry, employing a sulfuric acid blank, for both anionic and cationic compounds of this type has been described by Spada et al.[18] A gravimetric method employs conversion of the quaternary compounds to insoluble reineckates.[19,20] An alkali-metric method in which salts of organic bases are precipitated as tetraphenylboron compounds and then titrated with acid has been described as accurate between +1.6% and −3%, but most errors were much smaller.[21]

A gas–liquid chromatography method utilizing lithium aluminum hydride (LAH) has been described. The long-chain quaternary ammonium salts are reduced to tertiary amines with LAH. Subsequently, the amines are analyzed by temperature-programmed gas chromatography.[22] A method has also been developed for the rapid identification of quaternary ammonium derivatives; this involves (1) the use of a silver nitrate-nitric acid solution to detect the halide; (2) the determination of halide type; and (3) the determination of the halide's melting point to make the final differentiation.[23] It is possible to detect five cationic quaternary ammonium compounds by nuclear magnetic resonance. However, this methodology is more adapted to anionic compounds.[24] In order to identify quaternary compounds in the presence of many others, a semi-microtitration

technique has been developed using sodium lauryl sulfate in a chloroform/water two-phase system. The compounds are first separated on an ion-exchange column.[25]

Impurities

Table 2 lists the reported known impurities contained in Stearalkonium Chloride.

TABLE 2. Impurities.[a]

Chemical names of impurities	*Percent present in material*
Stearyl Alcohol	3–6
Stearyl Dimethylamine Hydrochloride	1.5–4 (combined)
Stearyl Dimethylamine	

[a]Data from Ref. 3.

PURPOSE AND FREQUENCY OF USE IN COSMETICS

In cosmetic products, Stearalkonium Chloride is primarily used as surface-active and antimicrobial agents. Because it has a high affinity for proteins, this material is quite serviceable in cosmetic products intended for use on the hair. Properties relevant to such use are presented in Table 3.

The categories of cosmetic products and the concentrations in which Stearalkonium Chloride is used appear in Table 4. The cosmetic product formulation computer printout which is made available by the Food and Drug Administration (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 true, effective concentration found in the finished product; the effective concentration in such a case would be a fraction of that reported to the FDA. The fact that data are only submitted within the framework

TABLE 3. Cosmetic Properties of Stearalkonium Chloride.[a]

Property	*Product type(s)*
Improvement of wet combing	Rinses, conditioners
Increased luster	Rinses, conditioners
Improvement of feel	Setting lotions, bleaches
Improvement of dry combing	Setting lotions, rinses, conditioners
Wetting power (leveling action)	Bleaches, dyes, setting lotions
Antistatic effect	All hair products
Foaming power	Special purpose shampoos
Hydrophobizing effect	All hair products

[a]Data from Ref. 1.

TABLE 4. Product Formulation Data on Stearalkonium Chloride.[a]

Cosmetic Product Type	*Concentration (%)*	*No. of product formulations*
Hair conditioners	>1–5	52
	>0.1–1	18
	≤0.1	8
Hair sprays (aerosol fixatives)	>0.1–1	4
	≤0.1	5
Hair straighteners	>0.1–1	1
Permanent waves	>1–5	1
	>0.1–1	3
	≤0.1	2
Rinses (noncoloring)	>1–5	55
	>0.1–1	5
Tonics, dressings, and other hair grooming aids	>1–5	1
	>0.1–1	2
	≤0.1	1
Wave sets	≤0.1	8
Other hair preparations	>0.1–1	2
	≤0.1	3
Hair dyes and colors (all types requiring caution statement and patch test)	>1–5	6
	>0.1–1	4
	≤0.1	11
Hair rinses (coloring)	>1–5	3
	>0.1–1	38
	≤0.1	6
Nail creams and lotions	>0.1–1	1
Aftershave lotions	≤0.1	1
Cleansing (cold creams, cleansing lotions, liquids and pads)	>1–5	1
	>0.1–1	1
Moisturizing	>1–5	4
	>0.1–1	1
Other skin care preparations	>1–5	1

[a]Data from Refs. 26, 27.

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 ten-fold error in the assumed ingredient concentration. The compounds are found in a variety of formulations, but are particularly prevalent in hair care products. Concentrations of use for Stearalkonium Chloride range from ≤0.1 to 5%.[26,27]

Stearalkonium Chloride is used in formulations that are applied to all areas of the skin, nails, and hair, and around the body orifices. Formulations containing this ingredient may be applied to the body as infrequently as once each month (hair dyes and colors) or as frequently as once or twice a day (tonics, dressings, and hair grooming aids). They may be in contact with various areas of the body for as little as a few minutes or as much as a few days. Occasional or daily use may extend over a period of years.

Potential Interactions with other Ingredients

The quaternary ammonium salt, Stearalkonium Chloride, is insoluble in water; it can be solubilized by adding an excess of anionics or cationics.[13] However, these solubilized materials cease to have the characteristic properties

of Stearalkonium Chloride. The cationic portion of the quaternary ammonium complex loses its microbial activity, while the anionic portion loses its foaming characteristics.[28] Stearalkonium Chloride is compatible with nonionic ingredients or compounds, is stable in hard water, and is a good emulsifying agent.

BIOLOGICAL PROPERTIES

General Effects

The antibacterial activity of cationic quaternary ammonium compounds varies wih the length of the alkyl chain, the greatest activity being associated with the C_{16} or C_{18} chain length (depending on the organism tested). This activity may increase with increased charge on the nitrogen atom, but may decrease if excessive atoms are clustered around it. Bactericidal activity tends to increase with critical micelle concentration,[29] although no direct correlation has been reported between the surfactant activity and bactericidal action.[29,30]

Standard antibacterial and antifungal tests were performed on a series of alkyldimethylammonium chlorides of C_{8-19} chain length. The most consistent amount of bactericidal and fungistatic activity was seen in compounds of C_{12-16} chain-length. The bactericidal action of a series of these compounds on a myxobacterium, pathogenic to fish, was greatest for the Hexadecyl compound.[31,32]

A 1% solution of Stearalkonium Chloride inhibited bacterial growth in a study of this material's germicidal activity. When tested for bacteriostatic efficiency against *Salmonella typhosa, Staphylococcus aureus,* and *Bacillus anthracis,* Stearalkonium Chloride was found to be an effective bacteriostat, particularly against *S. aureus.*[33,34]

Secondary Effects

The adjuvant activity of 203 aliphatic nitrogenous bases was evaluated through the use of diphtheria toxoid in guinea pigs. The toxoid was administered subcutaneously in the abdominal wall twice, at 28-day intervals. Dilutions were made to achieve a dose of 1 LF in 0.2 ml per injection. (LF = limit flocculation: that amount of dyphtheria toxoid which gives the most rapid flocculation when incubated with one standard unit of dyphtheria antitoxin.) A single 0.1 ml dose of each adjuvant was administered at the time of the first toxoid dose. Adjuvant activity required a combination of basicity and a long aliphatic chain length (C_{12}). Active compounds were hemolytic and produced damage to monkey kidney or human epitheloid (HEp^2) tissue culture mono-layers. Stearalkonium Chloride was highly active by virtue of its long alkyl chain.[35]

Concentrations of Stearalkonium Chloride producing 100% and 50% hemolysis of isolated erythrocytes from rabbits and sheep, respectively, have been determed to be 2.4×10^{-5} *M* and 3.0×15^{u} *M*.[36,37]

Absorption, Metabolism, Storage, and Excretion

A commercial mixture of alkylbenzyldimethylammonium (ABMA) chlorides (predominantly C_{12}, C_{14}, C_{16}) was administered orally, rectally, or intramuscularly to rabbits, dogs, and cats at 10 times the lethal dose. The concentrations in blood and various tissues were determined. After oral administration, most of the compound remained in the upper gastrointestinal tract, with small concentrations be-

ing found in the liver and blood. After rectal administration, nearly all the ABMA chloride was recovered from the lower bowel with small amounts from blood, liver, and kidney tissue. Following intramuscular administration, nearly all the mixture remained at the injection site. These results indicate that the ABMA chlorides are poorly absorbed and poorly distributed in the tissues.[38]

Animal Toxicology

General Studies

Oral toxicity: acute

Studies have failed to establish with certainty the LD50 of Stearalkonium Chloride in rats. Two separate experiments have been reported (Table 5). A 25% aqueous solution of pure Stearalkonium Chloride introduced by stomach tube into rats produced an LD50 value of greater than 0.5 g/kg but less than 1.25 g/kg. A second study reported Stearalkonium Chloride administered by gavage to have an LD50 value greater than 0.0625 g/kg but less than 1.25 g/kg for the pure ingredient.[39,40]

A seven-day oral LD50 in mice has been reported to be 0.76 ± 0.11 g/kg, according to the method of Hoppe and Lands, for pure Stearalkonium Chloride.[30] An aqueous solution containing 20% Stearalkonium Chloride and 5% stearyl alcohol was determined to have an LD50 of 4.0 ± 0.1 ml/kg in rats.[41]

Eye irritation: acute

The Draize procedure was used to determine the eye irritation index in rabbits of Stearalkonium Chloride at various concentrations. Table 6 presents a summary of the data from these experiments. The 25% solution is a severe irritant to the eye, while solutions of 1.25% or less are slightly and transiently irritating, with the effects being limited to the conjunctivae; these effects disappear after 3–4 days.[33,42-45]

A study was undertaken to determine the highest concentration of an aqueous solution containing a 4:1 ratio of Stearalkonium Chloride to stearyl alcohol that did not produce irritancy to rabbit eye mucosa in three or more of five test animals used. This threshold concentration was determined to be 0.04% Stearalkonium Chloride and 0.01% stearyl alcohol.[41]

Dermal irritation: acute

Adult rabbits were used in determining Stearalkonium Chloride's potential for skin irritation. Primary dermal irritation indices were calculated according to the Draize procedure for 25%, 2.5%, and 1.25% concentrations of the material.

TABLE 5. Oral LD50 in Rats.

Dose (g/kg pure Stearalkonium Chloride)	*Animals Dead/Total*	*LD50 (g/kg)*	*Ref.*
0.5	0/6	>0.5	39
1.25	4/6	<1.25	39
2.5	5/6	<2.5	39
0.0625	3/10	>0.0625	40
1.25	9/10	<1.25	40

TABLE 6. Primary Eye Irritation Scores in Rabbits.[a]

Concentration (%)	No. of Animals	Days 1	2	3	4	7	Ref.
Unwashed							
25.	6	33.5	37.8	35.5	36.8	73.8	41
1.25	6	14.7	10.0	3.2	1.0	0.0	41
2.5	6	10.7	6.7	3.0	–	0.0	42
2	3	7.3	4.0	0.67	0.0	0.0	43
4	3	28.0	24.0	24.0	–	–	44
2.5	6	max score of 16.7–blindness after 7th day					32
0.5	6	max score of 2.0–cleared after 3 days					32
Washed							
2.5	6	max score of 5.3–cleared after 4 days					32
0.5	6	0.0	0.0	0.0	0.0	0.0	32

[a]Total score possible/animal/observation interval = 110.

Applications of 0.5 ml of the test solutions were made to clipped areas of intact and abraded skin. The treated areas were covered with gauze and wrapped to keep the test material in contact with the skin and to decrease the rate of vaporization. The wrapping and test material were removed 24 hours following application and the sites examined and scored separately for erythema and edema at 24 and 72 hours. The mean scores for 24- and 72-hour readings were averaged to determine the irritation index. Primary irritation indices were calculated to be 6.0, 2.4, and 1.0 for the 25%, 1.25%, and 2.5% solutions, respectively.[46,47]

The effect of Stearalkonium Chloride on skin swelling was studied using guinea pigs. After being soaked in water for one hour, squares of stratum corneum were lifted out of the water and their dimensions were determined. The squares were then immersed in a 20% solution of Stearalkonium Chloride for 16 hours, after which their dimensions were again measured. Swelling was expressed as the percentage increase in area after exposure to the second solution. Twenty percent Stearalkonium Chloride produced swelling of 1.6%, while sodium lauryl sulfate at a concentration of 13.5% produced swelling of 13.1%.[48]

Fish toxicity

Blueback salmon fingerlings (2 inch) were exposed to solutions of Stearalkonium Chloride at 19 °C for one hour and then placed in fresh water for observation. The concentration at which all fish survived exposure for two days was 1:800,000.[32]

Subchronic studies: dermal irritation

Hair was clipped from the backs and sides of six albino rabbits. Two ml of an aqueous solution of a trade product containing 0.2% Stearalkonium Chloride and 0.05% stearyl alcohol was applied to the clipped area of the skin once daily, five days a week for four weeks. The condition of the skin was monitored carefully, as were signs of toxicity and weight loss in the animals. At the conclusion of the experiment, the animals were sacrificed and representative tissues were examined histopathologically. The product caused a mild and transient erythema of the skin, but in no case were systemic effects apparent.[41]

Myristalkonium Chloride was applied to rabbits in a 20-day subchronic der-

mal test. Two rabbits each were used at the dose levels of 4 and 1 ml/kg. Two control animals each received a dose of 400 ml/kg of water. The hair was clipped from the backs and flanks of the rabbits, and one-half of each test area was abraded while the remainder was left intact. An aqueous solution containing 800 ppm (0.08%) of pure Myristalkonium Chloride was applied daily for 20 consecutive days to 10% of the total body surface. After each application of the test material, the torsos of the rabbits were wrapped with a rubberized fabric to prevent possible ingestion and/or inhalation of the material. The animals were observed for 14 days after the last application. Minimal erythema appeared in the 4 ml/kg group on Day five, with minimal edema being evident on Day nine. On Day 11, the erythema became more pronounced, and it persisted, along with minimal edema, through the rest of the treatment. At the 1 ml/kg dose level, there was minimal hyperemia with no edema. Though the hyperemia increased slightly in intensity on Day 15, it became minimal again on Day 19 and remained so through the rest of the treatment. Minimal edema was observed in this group on Days 17–21. Minimal hyperemia was observed in the controls from Days 11–21. All rabbits showed complete recovery within four days after treatment was stopped.[49]

Chronic studies

An unidentified alkyldimethylbenzyl ammonium chloride surfactant compound at concentrations of 0.063, 0.125, 0.25, or 0.5% was fed to four groups of 12 male rats in their diet for two years. An equal number of rats were used as controls. The animals that received 0.5% died early in the study. As Table 7 shows, weight gains for the first year were reduced among those surviving animals that received the lower doses. The only gross or microscopic pathologic changes were ". . . produced by irritation of the gastrointestinal tract. To an extent which depended on the concentration of the surfactant agents in the diet, this irritation prevented proper nutrition. In severe cases of irritation, death resulted."[50]

Special Studies

Teratology

Albino rats were used to evaluate the teratogenic potential of a 50% solution of Myristalkonium Chloride. Virgin, adult female rats were mated with young adult males, and the detection of vaginal sperm plug was considered to be Day 0 of gestation. Beginning on the sixth day and continuing through Day 15 of gestation, each rat received an appropriate quantity of test material to achieve a dose

TABLE 7. Chronic Feeding of an Undiluted Alkyldimethylbenzylammonium Chloride.[a]

Dietary Dose (%)	*No. of animals*	*Mean wt gain (g)*	*Standard error of mean*	*Significance probability*
0	11	471.9	±13.2	–
0.063	10	455.5	±21.6	–
0.125	10	417.4	±16.4	<0.05
0.25	7	297.8	±31.2	<0.001

[a]Data from Ref. 49.

of 0, 10, 25, or 50 mg/kg/day. The gavage vehicle was water. Water and aspirin were used for the negative and positive controls, respectively. On Day 20 of gestation, each dam was sacrificed and the fetuses removed. Among the treated groups, neither reproduction performance of the dam nor fetus weights differed from those of the control animals. The incidences of any skeletal abnormality and soft tissue abnormalities were no greater in the Myristalkonium Chloride groups than in the control groups. The incidence of both types of abnormalities was significantly greater in the aspirin-treated group. On the basis of this study, investigators concluded that daily oral doses of 10, 25, or 50 mg/kg of Myristalkonium Choloride during days six through 15 of pregnancy did not produce any indication of teratogenicity.[51]

Clinical Assessment of Safety

Skin Irritation and Sensitization: The Shelanski repeated insult patch test was used to determine the irritation/sensitization potential of Stearalkonium Chloride in humans. Fifty volunteers were treated with a 1% solution in water for 15 applications and then given a challenge application. Zero readings were obtained for all subjects, for all induction applications, and for the challenge dose. At this concentration, the material was shown to be neither a primary irritant nor a sensitizer. In a 50-subject test, it is possible to achieve 95% certainty that the test material will only sensitize 0–6% of the population if none of the 50 subjects show any indication of sensitization. Since all readings were zero, it was concluded that this material at the specified concentration was safe for use in contact with the human skin.[52]

In a second study, a cotton patch saturated with an aqueous solution of 20% Stearalkonium Chloride and 5% stearyl alcohol was placed on the inner surface of the forearm of 50 human subjects. The patch was covered with aluminum foil which was held in place with adhesive tape. Forty-eight hours following application, the patch was removed and the area inspected for signs of primary irritation. The solution produced a definite erythema in some subjects (number not reported). Two weeks after the first patch had been applied, the procedure was repeated on the other arm to test for sensitization; none resulted. The Stearalkonium Chloride used in this study was not a highly purified material. The primary irritation may have been due to impurities in the material or to the stearyl alcohol vehicle;[41] however, the latest (1979) diagnostic patch-test data from the North American Contact Dermatitis Group indicate that 30 percent stearyl alcohol is at most a minimal sensitizer.[53] A 0.8% Stearalkonium Chloride solution did not provoke irritation or sensitization.[41]

SUMMARY

Stearalkonium Chloride is a cationic quaternary ammonium salt used in cosmetic products at concentrations of ≤ 0.1–5%. It appears in cosmetics primarily for its surfactant and anti-microbial properties.

Studies have failed to establish with certainty the oral LD50 of Stearalkonium Chloride in rats, the value falling between 0.5 and 1.25 g/kg. In mice, an LD50 value of 0.760–0.113 g/kg was reported in a seven-day oral study. In single application dermal studies with concentrations of up to 25%, Stearalkonium

Chloride produced minor irritation in rabbits. According to acute eye studies in rabbits, a 25% solution of the material was a severe irritant. Concentrations of 1.25% and less were slightly and transiently irritating to the rabbit eye.

A repeated insult patch test with a 1% aqueous solution of Stearalkonium Chloride on 50 human subjects showed the material to be neither a primary irritant nor a sensitizer. A single 48-hour patch test with challenge two weeks later indicated that 20% Stearalkonium Chloride was not a sensitizer.

No subchronic, chronic, carcinogenicity, mutagenicity, or teratogenicity animal testing data were available to the Panel, nor was there substantial information on the absorption, metabolism, storage, and excretion of Stearalkonium Chloride.

Human safety data, namely irritation and sensitization studies are limited, and there is an absence of photosensitization studies.

CONCLUSION

On the basis of the evidence at hand, the Expert Panel concludes that the cosmetic ingredient, Stearalkonium Chloride, is safe when incorporated in cosmetic products in concentrations similar to those presently marketed.

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TABLE 29
Stearalkonium Chloride use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentrations (Elder 1982)	2001 concentrations (CTFA 2001)
Bubble baths	—	5	—	—
Hair conditioners	78	107	≤0.1%–5%	0.7%–7%
Hair sprays (aerosol fixatives)	9	3	≤0.1%–1%	—
Hair Straighteners	1	—	>0.1%–1%	—
Permanent waves	6	2	≤0.1%–5%	—
Rinses (noncoloring)	60	5	>0.1%–5%	3%
Shampoos (noncoloring)	—	4	—	2%
Hair tonics, dressings, etc.	4	14	≤0.1%–5%	2%–3%
Wave sets	8	2	≤0.1%	—
Other hair preparations	5	3	≤0.1%–1%	2%
Hair dyes and colors	21	—	≤0.1%–5%	0.5%–2%
Hair rinses (coloring)	47	—	>0.1%–5%	—
Hair bleaches	—	—	—	0.4%
Nail creams and lotions	1	—	>0.1%–1%	—
Nail polish and enamel	—	1	—	—
Other personal cleanliness products	—	1	—	—
Aftershave lotions	1	—	≤0.1%	—
Skin cleansing preparations	2	—	>0.1%–5%	—
Body and hand skin care preparations	—	2	—	—
Moisturizing skin care preparations	5	1	>0.1%–5%	0.3%
Other skin care preparations	1	1	>1%–5%	—
Totals/ranges	249	151	≤0.1%–5%	0.3%–7%

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TABLE 30
Wheat Germ Glycerides use

Product category	1976 use (Elder 1980a)	2001 use (FDA 2001)	1976 concentrations (Elder 1980a)	2001 concentrations (CTFA 2001)
Eyeliner	—	—	—	0.05%–2%
Eye shadow	3	—	>0.1%–1%	2%
Other eye makeup preparations	4	—	≤0.1%–1%	—
Hair conditioners	—	—	—	0.001%
Hair tonics, dressings, etc.	—	—	—	0.1%
Face powders	2	—	>0.1%–1%	—
Foundations	9	—	≤0.1%–1%	2%
Lipstick	114	126	≤0.1%–5%	0.3%–25%
Makeup bases	6	—	≤0.1%–1%	—
Other makeup preparations	—	1	—	0.3%
Cuticle softeners	—	1	—	2%
Deodorants (underarm)	1	—	>0.1%–1%	—
Aftershave lotions	—	—	—	0.4%
Cleansing preparations (cold creams, cleansing lotions, liquids, and pads)	8	—	≤0.1%–1%	—
Face and neck skin care preparations[a]	12	—	>0.1%–5%	—
Body and hand skin care preparations[a]		—		—
Hormone (creams, lotions)[b]	1	—	>0.1%–1%	—
Moisturizing preparations[c]	24	—	≤0.1%–1%	—
Wrinkle smoothing (removers)[c]	1	—	≤0.1%	—
Night (creams, lotions)	11	—	≤0.1%–5%	—
Skin fresheners	1	—	≤0.1%	—
Other skin care preparations	15	—	>0.1%–1%	—
Totals/ranges	212	128	≤0.1%–5%	0.001%–25%

[a]Originally, Face and Neck and Body and Hand were combined as one category, but now they are separated.
[b]No longer a product category.
[c]Wrinkle smoothing (removers) are now part of the Moisturizing category.

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STEARALKONIUM CHLORIDE

A safety assessment of Stearalkonium Chloride was published in 1982 with the conclusion that this ingredient is "safe when incorporated in cosmetic products in concentrations similar to those presently marketed" (Elder 1982). New studies, along with the updated information regarding uses and use concentrations, were considered by the CIR Expert Panel. The Panel determined to not reopen this safety assessment.

In 1976, Stearalkonium Chloride was used in 249 cosmetic products, with the largest single use in rinses (noncoloring) in the concentration range of >0.1% to 5%. In 2001, Stearalkonium Chloride was used in 151 products (FDA 2001), with the largest single use reported for hair conditioners. The highest concentration of use was also in hair conditioners (0.7% to 7%) in 2001 (CTFA 2001). Table 29 presents the available use information.

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[2]Available from Director, Cosmetic Ingredient Review, 1101 17th Street NW, Suite 310, Washington, DC 20036, USA.

TABLE 31
Triticum Vulgare (Wheat) Gluten use

Product category	1976 use (Elder 1980a)	2001 use (FDA 2001)	1976 concentrations (Elder 1980a)	2001 concentrations (CTFA 2001)
Mascara	1	2	≤0.1%	—
Other shaving preparations	—	1	—	—
Other skin care preparations	—	2	—	—
Totals/ranges	1	5	≤0.1%	—

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WHEAT GERM GLYCERIDES AND WHEAT GLUTEN, WHEAT FLOUR AND WHEAT STARCH, AND WHEAT GERM OIL

Safety assessments of Wheat Germ Glycerides and Wheat Gluten were published in 1980 with the conclusion that these two ingredients were “safe when incorporated in cosmetic products and constitute no risk to the public in its present cosmetic use of these products” (Elder 1980a). Wheat Flour and Wheat Starch were found to be “safe as cosmetic ingredients in the present practices of use and concentration” (Elder 1980b). Wheat Germ Oil was also found “safe as a cosmetic ingredient in the present practices of use and concentration” (Elder 1980c). New studies, along with the updated information below regarding uses and use concentrations, were considered by the CIR Expert Panel. The Panel determined to not reopen these safety assessments.

TABLE 32
Triticum Vulgare (Wheat) Starch use

Product category	1976 use (Elder 1980b)	2001 use (FDA 2001)	1976 concentrations (Elder 1980b)	2001 concentrations (CTFA 2001)
Hair conditioners	—	1	—	0.01%–0.6%
Hair sprays (aerosol fixatives)	—	1	—	0.001%
Permanent waves	—	—	—	0.001%–0.2%
Shampoos (noncoloring)	—	—	—	0.001%–0.2%
Hair tonics, dressings, etc.	—	5	—	0.1%
Hair dyes and colors	—	19	—	—
Face powders	4	2	>5%–25%	0.1%
Foundations	—	—	—	3%
Bath soaps and detergents	—	—	—	25%
Skin cleansing preparations	—	1	—	0.03%
Face and neck skin care preparations	—	1	—	—
Body and hand skin care preparations	—	3	—	0.1%
Night skin preparations	—	1	—	—
Paste masks (mud packs)	—	4	—	—
Other skin care preparations	—	1	—	—
Totals/ranges	4	39	>5%–25%	0.001%–25%