

Annual Review of Cosmetic Ingredient Safety Assessments—2001/2002¹

The Cosmetic Ingredient Review (CIR) Expert Panel has assessed the safety of over 1100 cosmetic ingredients since its inception in 1976. The very first safety assessments were published in earlier incarnations of this journal—the *Journal of Environmental Pathology and Toxicology* in 1980, and the *Journal of the American College of Toxicology* from 1982 to 1996.

Because information relevant to the safety of ingredients may have become available since these early safety assessments were published, the CIR Expert Panel has initiated a re-review process. If new information is thought to be available or if a long period of time has passed, the CIR Expert Panel may initiate a search for relevant new data.

In some cases, newly available data are largely redundant with the data available in the original safety assessment. In other cases, there is new safety data. If after considering any newly available information, the CIR Expert Panel decides not to reopen a safety assessment, this finding, along with any background material, is summarized and announced publicly. To assure that the scientific community is aware of any new information and the decision not to reopen, this *Annual Review of Cosmetic Ingredient Safety Assessments* is prepared. This is the first such annual review.

For each original safety assessment, the re-review addresses the import of new studies that were considered by the CIR Expert Panel, if any were available. A reference list is provided that updates the references provided in the original safety assessment. The re-review also captures information on the industry's current practices of ingredient use, updating the data available in the earlier report. Although this material provides the opinion of the CIR Expert Panel regarding the new data described, it does not constitute a full safety review.

The ingredients the CIR Expert Panel considered through June of 2002 and decided not to reopen are:

Aluminum Distearate
Aluminum Stearate
Aluminum Tristearate
Ammonium Stearate
Avocado Oil (aka Persea Gratissima (Avocado) Oil)

Calcium Stearate
Caprylic/Capric Triglyceride
Carbomers
Decyl Oleate
Glycol Stearate
Glycol Stearate SE
Glycol Distearate
Imidazolidinyl Urea
Isodecyl Oleate
Isopropyl Lanolate
Lithium Stearate
Magnesium Stearate
Potassium Stearate
Quaternium-18
Quaternium-18 Hectorite
Quaternium-18 Bentonite
Sodium Stearate
Squalene
Squalane
Stearylalkonium Chloride
Wheat Germ Glycerides
Wheat Gluten (aka Triticum Vulgare (Wheat) Gluten)
Wheat Flour (aka Triticum Vulgare (Wheat) Kernel Flour)
Wheat Starch (aka Triticum Vulgare (Wheat) Starch)
Wheat Germ Oil (aka Triticum Vulgare (Wheat) Germ Oil)
Zinc Stearate

AVOCADO OIL (aka PERSEA GRATISSIMA (AVOCADO) OIL)

A safety assessment of Avocado Oil was published in 1980 with the conclusion "safe for use as presently incorporated into cosmetic formulations" (Elder 1980). Studies available since that safety assessment was completed, 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.

The CIR Expert Panel discussion focused on the new studies reporting the co-occurrence of latex and avocado allergies. Because the oil derived from the avocado has no protein component, Persea Gratissima (Avocado) Oil used in cosmetics is not expected to cross-react in individuals who are allergic to latex.

The Panel noted that a long history of reviewing plant-derived or "botanical" cosmetic ingredients has developed since these

Received 4 December 2002; accepted 18 March 2003.

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TABLE 1
Persea Gratissima (Avocado) Oil use

Product category	1976 use (Elder 1980)	2001 use (FDA 2001)	1976 concentrations (Elder 1980)	2001 concentrations (CTFA 2001)
Bath oils, tablets, and salts	1	5	>0.1%–1%	0.1%–5%
Bubble baths	—	—	—	0.5%
Other bath preparations	1	—	>1%–5%	0.1%–0.5%
Eyeline	3	—	>0.1%–1%	0.1%
Eye shadow	1	1	>0.1%–1%	0.1%–0.5%
Eye lotion	1	3	≤0.1%	—
Eye makeup remover	1	2	>0.1%–1%	3%
Mascara	—	—	—	0.1%
Other eye makeup preparations	1	2	≤0.1%	—
Powders	—	1	—	3%
Other fragrance preparations	—	1	—	—
Hair conditioners	7	6	>0.1%–5%	1%–3%
Hair sprays (aerosol fixatives)	—	—	—	0.02%
Permanent waves	2	1	≤0.1%	—
Rinses (noncoloring)	—	—	—	.03%
Shampoos (noncoloring)	3	—	≤0.1%–5%	—
Hair tonics, dressings, etc.	—	3	—	0.1%–0.3%
Wave sets	1	—	≤0.1%	—
Other hair preparations	—	1	—	—
Hair dyes and colors	—	8	—	—
Blushers (all types)	—	3	—	0.1%–0.3%
Face powders	—	—	—	0.2%–3%
Foundations	2	—	>1%–5%	0.2%–3%
Leg and body paints	—	4	—	—
Lipstick	157	29	≤0.1%–50%	0.7%–21%
Makeup bases	2	4	>0.1%–1%	—
Rouges	1	—	>1%–5%	—
Other makeup preparations	6	1	>1%–5%	3%
Cuticle softeners	—	2	—	19%
Nail creams and lotions	—	—	—	4%
Other manicuring preparations	—	2	—	0.4%–4%
Bath soaps and detergents	—	—	—	0.1%–5%
Aftershave lotion	—	1	—	0.001%–0.01%
Beard softeners	—	—	—	1%
Other shaving preparations	—	—	—	0.1%
Skin cleansing preparations	9	13	>0.1%–10%	0.3%–3%
Depilatories	—	—	—	2%
Face and neck skin care preparations ^a	11	13	>0.1%–5%	7%–23%
Body and hand skin care preparations ^a	—	23	—	0.01%–5%
Foot powders and sprays	—	—	—	0.5%
Moisturizing preparations ^b	—	23	—	0.01%–2%
Wrinkle smoothing (removers) ^b	16	—	>0.1%–50%	—
Night creams, lotions, etc.	7	5	>0.1%–5%	0.5%–2%
Paste masks (mud packs)	3	4	>1%–5%	0.5%–2%
Other skin care preparations	2	16	>0.1%–25%	0.5%–1%
Suntan gels, creams, and liquids	2	5	>1%–5%	4%
Indoor tanning preparations	—	1	—	0.5%
Other suntan preparations	—	3	—	0.5%
Totals/ranges	240	188	≤0.1%–50%	0.001%–23%

^aOriginally, Face and Neck and Body and Hand were combined as one category, but now they are separated.

^bWrinkle smoothing (removers) are now part of the Moisturizing category.

ingredients were first considered. As a result of that experience, it is now common to remind manufacturers that cosmetic products containing plant-derived ingredients should be formulated to limit the presence of pesticide/heavy metal residues as follows: lead ≤ 0.1 ppm; arsenic ≤ 3 ppm; mercury ≤ 1 ppm; total polychlorobiphenyl (PCB)/pesticide contamination ≤ 40 ppm, with ≤ 10 ppm for any specific residue (Andersen 1998).

The terminology for this ingredient in the *International Cosmetic Ingredient Dictionary and Handbook* (Pepe, Wenninger, and McEwen 2002) has changed. Avocado Oil is currently Persea Gratissima (Avocado) Oil. This ingredient was used in 240 cosmetic products in 1976. The highest concentrations were in lipsticks. In 2001, 188 uses were reported to the Food and Drug Administration (FDA) (2001), with lipstick concentrations reported by the Cosmetic, Toiletry, and Fragrance Association (CTFA) still the highest of any product type (CTFA 2001). Table 1 presents the available use information.

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

CAPRYLIC/CAPRIC TRIGLYCERIDE

A safety assessment of Caprylic/Capric Triglyceride was published in 1980 with the conclusion “safe when incorporated in amounts similar to those presently marketed” (Elder 1980). New studies, along with updated information regarding uses and use concentrations, were considered by the CIR Expert Panel. The Panel determined to not reopen this safety assessment.

The CIR Expert Panel noted that recent safety test data are presented in a safety assessment of Trilaurin and 22 other

triglycerides completed in 1999, with the conclusion that those triglycerides are safe as used in cosmetic formulations (CIR 1999).

In 1976, Caprylic/Capric Triglyceride was used in 550 cosmetic products, with the largest single use in lipsticks in the concentration range of >1% to 25%. In 2001, uses in 763 products were reported to FDA (2001) and the largest single use was in eyeliner products at a maximum concentration of 35% (CTFA 2001). Table 2 presents the available use information.

TABLE 2
Caprylic/Capric Triglyceride use

Product category	1976 use (Elder 1980)	2001 use (FDA 2001)	1976 concentrations (Elder 1980)	2001 concentrations (CTFA 2001)
Baby lotions, oils, powders, etc.	—	2	—	0.8%
Bath oils, tablets, and salts	2	—	>0.1%–5%	25%–78%
Other bath preparations	1	—	>1%–5%	7%–10%
Eyebrow pencil	—	9	—	4%–19%
Eyeliner	—	131	—	0.5%–35%
Eye shadow	134	33	>0.1%–50%	0.03%–49%
Eye lotion	—	4	—	2%–10%
Eye makeup remover	—	2	—	6%–10%
Mascara	—	—	—	0.008%
Other eye makeup preparations	4	28	>5%–50%	6%–18%
Colognes and toilet waters	4	1	>0.1%–1%	7%
Perfumes	39	7	>5%–50%	9%–84%
Other fragrance preparations	28	22	>5%–10%	7%–33%
Hair conditioners	1	4	>1%–5%	1%–5%
Hair sprays (aerosol fixatives)	1	—	>1%–5%	0.00005%–0.02%
Hair straighteners	—	1	—	—
Shampoos (noncoloring)	1	1	>0.1%–1%	0.02%–0.5%
Hair tonics, dressings, etc.	1	4	>1%–5%	0.0001%–18%
Other hair preparations (noncoloring)	—	—	—	— ^a
Hair rinses (coloring)	—	1	—	—
Blushers (all types)	24	18	>5%–>50%	5%–33%
Face powders	—	11	—	0.01%–22%
Foundations	23	18	>0.1%–50%	1%–21%
Lipstick	167	75	>1%–25%	0.1%–54%
Makeup bases	4	13	>5%–25%	8%–13%
Rouges	8	2	>5%–10%	4%–7%
Makeup fixatives	1	4	>25%–50%	—
Other makeup preparations	—	26	—	12%–17%
Cuticle softeners	—	2	—	5%
Nail creams and lotions	2	—	>5%–50%	—
Nail polish and enamel	—	—	—	12%
Nail polish and enamel removers	—	2	—	2%–5%
Other manicuring preparations	—	1	—	0.2%–15%
Dentifrices	—	—	—	0.002%
Bath soaps and detergents	—	—	—	0.3%
Deodorants (underarm)	2	1	>0.1%–1%	0.00001%–5%
Other personal cleanliness products	—	—	—	0.3%–1%
Aftershave lotion	2	4	>1%–5%	2%–5%
Shaving cream	2	—	>1%–5%	—

(Continued on next page)

TABLE 2
Caprylic/Capric Triglyceride use (*Continued*)

Product category	1976 use (Elder 1980)	2001 use (FDA 2001)	1976 concentrations (Elder 1980)	2001 concentrations (CTFA 2001)
Other shaving preparation products	1	1	>1%–5%	2%
Skin cleansing preparations	4	33	>0.1%–25%	2%–9%
Face and neck skin care preparations ^b	—	36	—	1%–48%
Body and hand skin care preparations ^b	14	68	>0.1%–25%	0.06%–45% ^c
Foot powders and sprays	—	—	—	18%
Moisturizing preparations ^d	59	95	>1%–10%	0.002%–10%
Wrinkle smoothing (removers) ^d	1	—	>0.1%–1%	—
Night creams, lotions, etc.	2	31	>1%–10%	2%–12%
Paste masks (mud packs)	—	14	—	2%–6%
Skin fresheners	—	—	—	6%
Other skin care preparations	3	38	>1%–50%	9%–51%
Suntan gels, creams, and liquids	12	4	>0.1%–25%	2%–11%
Indoor tanning preparations	—	12	—	0.6%–5%
Other suntan preparations	3	4	>0.1%–25%	4%–19%
Totals/ranges	550	763	>0.1%–50%	0.00001%–84%

^aReported to be in use, but no concentration of use was provided.

^bOriginally, Face and Neck and Body and Hand were combined as one category, but now they are separated.

^c43% in a spray product.

^dWrinkle smoothing (removers) are now part of the Moisturizing category.

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CARBOMER 934, 910, 934P, 940, 941, AND 962

A safety assessment of Carbomers 934, 910, 934P, 940, 941, and 962 was published in 1982 with the conclusion “are safe as cosmetic ingredients in the present practices of use and con-

centration” (Elder 1982). New studies, along with the updated information in Tables 3 to 6 regarding uses and use concentrations, were considered by the CIR Expert Panel. The Panel determined to not reopen this safety assessment.

The CIR Expert Panel acknowledged the potential aerosol use of Carbomers 934 and 940. The effects of inhaled aerosols depend on the specific chemical species, the concentration, the duration of exposure, and site of deposition within the respiratory system. Particle size is the most important factor affecting the location of deposition (Jensen and O’Brien 1993). The mean aerodynamic diameter of pump hair spray particles is $\leq 80 \mu$, and the diameter of anhydrous hair spray particles is 60 to 80μ . Typically less than 1% are below 10μ , which is the upper limit for respirable particles (Bower 1999). Based on the particle size, Carbomers 934 and 940 would not be respirable in formulation.

The Panel acknowledged the industry practice of removing benzene from Carbomers. Resulting levels should be below those shown to have no risk to human health. For example, the Environmental Protection Agency (EPA) has established for drinking water that the 10^{-6} risk level for cancer is between 1 and $10 \mu\text{g/L}$ (EPA 2002).

The current terminology in the *International Cosmetic Ingredient Dictionary and Handbook* is Carbomers, the number extensions appear only as technical names (Pepe, Wenninger, and McEwen 2002). Carbomers 910 and 962 were not used in either 1976 or 2001.

TABLE 3
Carbomer 934 use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentration (Elder 1982)	2001 carbomers concentration ^a (CTFA 2001)
Baby shampoos	—	9	—	—
Baby lotions, oils, powders, etc.	6	—	$\leq 1\%$	0.2%–0.8%
Other baby products	—	1	—	0.3%
Other bath preparations	7	—	$>0.1\%$ –25%	0.1%–1%
Eyebrow pencil	—	1	—	—
Eyeliners	5	4	$>0.1\%$ –1%	0.2%
Eye shadow	20	—	$>0.1\%$ –1%	0.4%–0.7%
Eye lotion	—	1	—	0.4%–2%
Mascara	1	1	$\leq 0.1\%$	0.7%–1%
Other eye makeup preparations	—	18	—	0.7%–1%
Perfumes	9	9	$>0.1\%$ –1%	0.3%–0.8%
Sachets	11	9	$\leq 1\%$	0.8%
Other fragrance preparations	5	10	$>0.1\%$ –1%	0.7%–1%
Hair conditioners	3	3	$>0.1\%$ –1%	0.8%–0.9%
Hair sprays (aerosol fixatives)	—	1	—	—
Permanent waves	1	—	$>0.1\%$ –1%	—
Shampoos (non-coloring)	1	5	$\leq 0.1\%$	0.3%–1.5%
Hair tonics, dressings, etc.	8	12	$>0.1\%$ –5%	0.7%–1.5%
Wave sets	1	—	$>0.1\%$ –1%	—
Other hair preparations	4	1	$>0.1\%$ –5%	0.7%

(Continued on next page)

TABLE 3
Carbomers 934 use (*Continued*)

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentration (Elder 1982)	2001 carbomers concentration ^a (CTFA 2001)
Hair dyes and colors	1	7	>0.1%–1%	0.8%–2%
Hair bleaches	—	11	—	—
Other hair coloring preparations	1	—	>0.1%–1%	0.7%
Blushers (all types)	14	—	>0.1%–5%	0.8%–2%
Foundations	13	—	>0.1%–5%	0.001%–1%
Makeup bases	4	—	≤1%	0.5%
Rouges	6	—	>0.1%–25%	0.3%
Makeup fixatives	1	—	≤0.1%	0.3%
Other makeup preparations	2	1	>0.1%–1%	0.5%–2%
Cuticle softeners	3	—	>0.1%–1%	1.2%
Dentrifices	1	—	>0.1%–1%	0.7%–0.5%
Bath soaps and detergents	1	1	>0.1%–1%	0.003%–2%
Deodorants (underarm)	1	—	≤1%	—
Other personal cleanliness products	1	1	>0.1%–1%	0.3%–1%
Aftershave lotion	8	9	>0.1%–1%	0.1%–0.6%
Beard softeners	1	—	>0.1%–1%	—
Shaving cream	4	2	>0.1%–1%	0.1%–0.5%
Other shaving preparation products	3	3	≤3%	0.1%–0.5%
Skin cleansing preparations	40	49	≤5%	0.12%
Face and neck skin care preparations ^b	88	40	≤5%	0.1%–1%
Body and hand skin care preparations ^b	—	127	≤5%	0.05%–0.8%
Foot powders and sprays	—	1	—	0.3%–0.7%
Moisturizing preparations ^c	147	135	≤5%	0.1%–0.9%
Wrinkle smoothing (removers) ^c	4	—	>0.1%–1%	—
Night creams, lotions, etc.	20	32	≤5%	0.003%–2%
Paste masks (mud packs)	7	17	≤0.1%	0.5%–1%
Skin fresheners	—	1	—	0.2%
Other skin care preparations	10	70	≤5%	0.02%–2%
Suntan gels, creams, and liquids	16	10	≤5%	0.2%–1%
Indoor tanning preparations	—	8	—	0.1%–0.4%
Other suntan preparations	—	1	—	0.3%
Totals/ranges	477	611	≤1%–25%	0.001%–2%

^aConcentrations reported only for “Carbomers.”

^bOriginally, Face and Neck and Body and Hand were combined as one category, but now they are separated.

^cWrinkle smoothing (removers) are now part of the Moisturizing category.

TABLE 4
Carbomer 934P use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentration (Elder 1982)	2001 carbomers concentration ^a (CTFA 2001)
Other bath preparations	1	—	>0.1–1%	0.1–1%
Moisturizing preparations	2	2	>0.1–1%	0.1–0.9%
Night creams, lotions, etc.	1	—	>0.1–1%	0.003–2%
Totals/ranges	4	2	>0.1–1%	0.003–2%

^aConcentrations reported only for “Carbomers.”

TABLE 5
Carbomer 940 use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentration (Elder 1982)	2001 carbomers concentration ^a (CTFA 2001)
Baby lotions, oils, powders, etc.	—	2	—	0.2%–0.8%
Other bath preparations	—	3	—	0.1%–1%
Eyebrow pencil	—	1	—	—
Eyeliner	1	4	≤0.1%	0.2%
Eye shadow	2	—	>0.1%–1%	0.4%–0.7%
Eye lotion	—	5	—	0.4%–2%
Eye makeup remover	1	1	>0.1%–1%	0.2%–0.5%
Mascara	1	2	>0.1%–1%	0.7%–1%
Other eye makeup preparations	1	17	>0.1%–1%	0.7%–1%
Colognes and toilet waters	16	1	>0.1%–5%	0.5%
Perfumes	1	—	>0.1%–1%	0.3%–0.8%
Powders	—	1	—	0.3%
Sachets	4	—	>0.1%–1%	0.8%
Other fragrance preparations	21	18	≤5%	0.7%–1%
Hair conditioners	6	5	>0.1%–5%	0.8%–0.9%
Hair sprays (aerosol fixatives)	—	2	—	—
Permanent waves	—	2	—	—
Shampoos (noncoloring)	—	4	—	0.3%–1.5%
Hair tonics, dressings, etc.	20	4	≤5%	0.7%–1.5%
Wave sets	41	16	≤5%	—
Other hair preparations	3	29	>0.1%–1%	0.7%
Hair dyes and colors	—	7	—	0.8%–2%
Blushers (all types)	30	8	>0.1%–5%	0.8%–2%
Foundations	6	5	>0.1%–1%	0.001%–1%
Leg and body paints	1	2	>1%–5%	0.4%
Makeup bases	1	—	>0.1%–1%	0.4%
Rouges	9	1	>0.1%–1%	0.3%
Cuticle softeners	2	2	≤1%	0.2%
Other manicuring preparations	—	2	—	0.2%–2%
Dentrifices	—	6	—	0.1%–0.5%
Other personal cleanliness products	1	7	>0.1%–1%	0.3%–1%
Aftershave lotion	9	37	>0.1%–5%	0.1%–0.6%
Preshave lotions (all types)	—	2	—	—
Other shaving preparation products	—	11	—	0.1%–0.5%
Skin cleansing preparations	28	43	≤5%	0.1%–2%
Face and neck skin preparations ^b	42	36	≤5%	0.1%–1%
Body and hand skin preparations ^b	—	101	—	0.05%–0.8%
Foot powders and sprays	1	4	>0.1%–1%	0.3%–0.7%
Moisturizing creams, etc. ^c	46	101	≤25%	0.1%–0.9%
Wrinkle smoothing (removers) ^c	1	—	>0.1%–1%	—
Night creams, lotions, etc.	25	18	>0.1%–5%	0.003%–2%
Paste masks (mud packs)	10	23	≤1%	0.5%–1%
Skin fresheners	9	7	≤1%	0.2%
Other skin care preparations	19	73	≤1%	0.02%–2%
Suntan gels, creams, and liquids	8	26	>0.1%–5%	0.2%–1%
Indoor tanning preparations	2	2	>0.1%–1%	0.1%–0.4%
Other suntan preparations	3	6	>0.1%–1%	0.3%
Totals/ranges	382	651	≤1%–5%	0.02%–2%

^aConcentrations reported only for “Carbomers.”

^bOriginally, Face and Neck and Body and Hand were combined as one category, but now they are separated.

^cWrinkle smoothing (removers) are now part of the Moisturizing category.

TABLE 6
Carbomer 941 use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentration (Elder 1982)	2001 carbomers concentration ^a (CTFA 2001)
Baby lotions, oils, powders, etc.	—	3	—	0.2%–0.8%
Bubble baths	3	1	≤1%	0.5%
Other bath preparations	1	3	>0.1%–1%	0.1%–1%
Eye lotion	1	—	>0.1%–1%	0.4%–2%
Eye shadow	1	—	≤1%	0.4%–0.7%
Eye makeup remover	1	7	≤0.1%	0.2%–0.5%
Other eye makeup preparations	—	1	—	0.7%–1%
Colognes and toilet waters	8	—	>0.1%–1%	0.5%
Perfumes	4	1	≤5%	0.3%–0.8%
Sachets	12	—	>0.1%–10%	0.8%
Other fragrance preparations	21	8	≤5%	0.7%–1%
Hair conditioners	1	—	>0.1%–1%	0.8%–0.9%
Permanent waves	—	1	—	—
Shampoos (noncoloring)	—	1	—	0.3%–1.5%
Hair tonics, dressings, etc.	3	1	≤1%	0.7%–1.5%
Wave sets	1	—	>0.1%–1%	—
Other hair preparations	4	—	>0.1%–1%	0.7%
Hair dyes and colors	—	31	—	0.8%–2%
Other hair coloring preparations	4	1	>0.1%–1%	0.7%
Blushers (all types)	2	—	≤1%	0.8%–2%
Lipsticks	1	—	>0.1%–1%	0.4%
Makeup bases	2	—	≤1%	0.5%
Other makeup preparations	—	1	—	0.5%–2%
Cuticle softeners	—	2	—	1.2%
Nail creams and lotions	1	1	≤1%	0.3%
Other manicuring preparations	1	—	>25%–50%	0.2%–2%
Bath soaps and detergents	—	4	—	0.003%–2%
Aftershave lotion	8	12	≤1%	0.1%–0.6%
Other shaving preparation products	3	7	≤1%	0.1%–0.5%
Cleansing creams, etc.	24	40	≤1%	0.1%–2%
Face and neck skin care preparations ^b	44	16	≤5%	0.1%–1%
Body and hand skin care preparations ^b	—	89	—	0.05%–0.8%
Foot powders and sprays	—	2	—	0.3%–0.7%
Moisturizing preparations	51	63	≤1%	0.1%–0.9%
Night creams, lotions, etc.	3	3	≤0.1%	0.003%–2%
Paste masks (mud packs)	—	3	—	0.5%–1%
Skin fresheners	6	1	≤1%	0.2%
Other skin care preparations	6	28	≤25%	0.02%–2%
Suntan gels, creams, and liquids	2	8	≤1%	0.2%–1%
Indoor tanning preparations	—	1	—	0.1%–0.4%
Other suntan preparations	—	6	—	0.3%
Totals/ranges	221	346	≤1%–25%	0.001%–2%

^aConcentrations reported only for “Carbomers.”

^bOriginally, Face and Neck and Body and Hand were combined as one category, but now they are separated.

Carbomer 934

Carbomer 934 was used in 477 cosmetic products in 1976, with the highest concentration range of >0.1 to 25% in other bath preparations. In 2001, Carbomer 934 was used in 611 cosmetic products (FDA 2001). Concentration of use data from 2001 were provided only for Carbomers as a group (CTFA 2001). Table 3 presents the available use information on Carbomer 934.

Carbomer 934P

Carbomer 934P was used in four cosmetic products in 1976. In 2001, usage was down to two products (FDA 2001). Concentration of use data from 2001 were provided only for Carbomers as a group (CTFA 2001). Table 4 presents the available use information on Carbomer 934P.

Carbomer 940

Carbomer 940 was used in 382 cosmetic products in 1976, with the highest concentration of ≤25% in moisturizing creams, liquids, powders, and sprays. In 2001, Carbomer 940 was used in 651 cosmetic products (FDA 2001). Concentration of use data from 2001 were provided only for Carbomers as a group (CTFA 2001). Table 5 presents the available use information.

Carbomer 941

Carbomer 941 was used in 221 cosmetic products in 1976, with the highest concentration range of >25% to 50% in other manicuring products. In 2001, Carbomer 941 was used in 346 cosmetic products (FDA 2001). Concentration of use data from 2001 were provided only for Carbomers as a group (CTFA 2001). Table 6 presents the available use information for Carbomer 941.

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DECYL AND ISODECYL OLEATE

A safety assessment of Decyl and Isodecyl Oleate was published with the conclusion that these ingredients are “safe in the concentrations of present practices and use in cosmetics” (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.

Decyl Oleate

Decyl Oleate was used in 128 products in 1976, with the largest uses in eyeshadows in the concentration range of 1% to 25%. In 2001, Decyl Oleate was reportedly used in 147 preparations, with the largest single use in body and hand preparations (FDA 2001). Concentration of use data from 2001 was provided (CTFA 2001). Complete information is shown in Table 7.

TABLE 7
Decyl Oleate use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentrations (Elder 1982)	2001 concentrations (CTFA 2001)
Baby lotions, oils, powders, etc.	1	—	>1%–5%	—
Bath oils, tablets and salts	2	1	>5%–25%	—
Eyeshadow	27	—	>1%–25%	13%
Eye lotion	—	1	—	—
Eye makeup remover	1	—	>1%–5%	—
Mascara	1	—	>0.1%–1%	—
Other eye makeup preparations	2	—	>50%	—
Hair conditioners	3	4	>0.1%–1%	—
Hair sprays	1	2	>0.1%–1%	—
Rinses (noncoloring)	1	—	>0.1%–1%	—
Shampoos (noncoloring)	1	—	>0.1%–1%	—
Hair dyes and colors	—	—	—	3%
Hair bleaches	—	—	—	3%
Blushers	4	1	>1%–10%	—
Face powders	—	1	—	—
Foundations	9	—	>0.1%–10%	5%
Lipstick	12	1	>1%–5%	8%
Makeup bases	6	—	>1%–10%	—
Other makeup preparations	1	—	>1%–5%	—
Nail creams and lotions	—	1	—	—
Other manicuring preparations	1	2	>5%–10%	—
Deodorants	—	1	—	—
Feminine hygiene deodorants	—	—	—	88%
Aftershave lotion	—	2	—	—
Skin cleansing preparations	10	11	≤0.1%–25%	1%
Face and neck skin care preparations ^a	—	24	—	—
Body and hand skin care preparations ^a	12	31	>1%–25%	1%–2%
Foot powders and sprays	—	1	—	—
Moisturizing preparations	23	20	>0.1%–25%	0.5%–4%
Night creams, lotions, etc.	1	17	>1%–5%	—
Paste masks (mud packs)	—	10	—	3%
Other skin care preparations	5	10	>1%–>50%	—
Suntan gels, creams, and liquids	4	5	>1%–50%	—
Indoor tanning preparations	—	1	—	6%
Totals/ranges	128	147	≤0.1%–>50%	0.5%–88%

^aOriginally, Face and Neck and Body and Hand were combined as one category, but now they are separated.

TABLE 8
Isodecyl Oleate use

Product category	1976 use (CIR 1982)	2001 use (FDA 2001)	1976 concentrations (CIR 1982)	2001 concentrations (CTFA 2001)
Bath oils, tablets and salts	1	—	>5%–10%	—
Other bath preparations	1	—	>0.1%–1%	—
Eyeshadow	8	—	>1%–5%	2%
Eye makeup remover	—	1	—	2%
Hair conditioners	—	3	—	—
Hair tonics, dressings, etc.	—	—	—	2%
Hair sprays	—	1	—	—
Blushers	1	—	>1%–5%	8%
Foundations	2	1	>1%–5%	5%
Lipstick	—	22	—	4%–8%
Other makeup preparations	2	2	>1%–5%	5%
Other manicuring preparations	—	1	—	—
Deodorants	1	—	>1%–5%	2%
Other personal cleanliness products	1	—	>1%–5%	—
Aftershave lotion	—	3	—	—
Other shaving preparation products	—	1	—	—
Skin cleansing preparations	1	2	>10%–25%	3%
Face and neck skin care preparations ^a	2	—	>5%–25%	2%–5%
Body and hand skin care preparations ^a	—	1	—	4%
Moisturizing preparations	4	5	>1%–10%	2%–3%
Night creams, lotions, etc.	—	1	—	5%
Other skin preparations	—	—	—	3%–4%
Suntan gels, creams, and liquids	—	—	—	3%
Totals/ranges	24	44	>0.1%–25%	2%–8%

^aOriginally, Face and Neck and Body and Hand were combined as one category, but now they are separated.

Isodecyl Oleate

Isodecyl Oleate was used in 24 cosmetic products in 1976, with the largest uses in eyeshadows in the >1% to 5% concentration range. In 2001, Isodecyl Oleate was used in 44 preparations, with the largest single use in lipsticks (FDA 2001). Concentration of use data from 2001 was provided (CTFA 2001). Complete Isodecyl Oleate information is shown in Table 8.

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GLYCOL STEARATE, GLYCOL STEARATE SE, AND GLYCOL DISTEARATE

A safety assessment of Glycol Stearate, Glycol Stearate SE, and Glycol Distearate was published in 1982 with the conclusion that these ingredients “are safe as cosmetic ingredients in the present practices of use and concentrations” (Elder 1982). New studies, along with the updated information below regarding types and concentrations of use were considered by the CIR Expert Panel. The Panel determined to not reopen this safety assessment.

Glycol Stearate

Glycol Stearate was used in 284 formulations in 1976, at concentrations from ≤0.1% to 10%. In 2001, there were 424 formulations reported to the FDA that contained Glycol Stearate (FDA 2001). Glycol Stearate was reported to be used in 16 new product categories and no longer used in 11 categories as compared to the 1976 FDA database. Concentration of use data from 2001 was provided (CTFA 2001). Table 9 presents the available use information for Glycol Stearate.

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

TABLE 9
Glycol Stearate use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentrations (Elder 1982)	2001 concentrations (CTFA 2001)
Baby lotions, oils, powders, etc.	—	—	—	5%
Other baby products	—	1	—	—
Bath oils, tablets, and salts	6	4	>0.1%–1%	—
Bubble baths	47	20	>0.1%–5%	2%
Other bath preparations	6	12	>0.1%–1%	0.2%–5%
Eyebrow pencil	3	—	>1%–5%	5%
Eyeliner	9	—	>1%–5%	4%
Eye shadow	76	—	>1%–10%	6%
Mascara	2	—	>1%–5%	3%
Perfumes	—	—	—	4%
Powders (dusting and talcum)	—	—	—	4%
Sachets	—	—	—	4%
Other fragrance preparations	—	1	—	2%
Hair conditioners	2	17	>5%–10%	0.0001%–3%
Hair straighteners	4	—	>5%–10%	—
Permanent Waves	—	1	—	—
Rinses (noncoloring)	3	—	>0.1%–1%	—
Shampoos (noncoloring)	77	149	≤0.1%–10%	0.05%–4%
Hair tonics, dressings, etc.	1	2	>1%–5%	1%
Hair dyes and colors	—	32	—	2%–6%
Hair shampoos (coloring)	2	1	>1%–5%	—
Blushers (all types)	5	—	>1%–5%	2%
Foundations	88	2	>1%–5%	4%
Leg and body paints	—	—	—	2%
Lipstick	1	1	>1%–5%	—
Makeup bases	2	—	>1%–5%	—
Rouges	8	—	>1%–5%	2%
Makeup fixatives	—	—	—	2%
Other makeup preparations	2	—	>1%–5%	2%–3%
Cuticle softeners	—	1	—	—
Nail creams and lotions	—	1	—	—
Nail polish and enamel removers	—	1	—	—
Other manicuring preparations	—	—	—	0.02%
Bath soaps and detergents	2	40	>0.1%–5%	0.3%–5%
Deodorants (underarm)	—	2	—	—
Douches	—	1	—	—
Other personal cleanliness products	—	8	—	0.2%–6%
Aftershave lotions	1	—	>0.1%–1%	—
Shaving cream	—	3	—	1%
Skin cleansing preparations	8	21	>0.1%–5%	0.2%–5%
Face and neck skin preparations ^a	11	8	>0.1%–5%	5%
Body and hand skin preparations ^a	—	24	—	0.7%–5%
Foot powders and sprays	—	4	—	5%
Moisturizing preparations	12	27	>0.1%–10%	5%
Night preparations	—	4	—	3%
Paste masks (mud packs)	—	3	—	—
Other skin care preparations	5	26	>0.1%–10%	3%–4%
Suntan gels, creams, and liquids	1	5	>1%–5%	—
Indoor tanning preparations	—	1	—	—
Other suntan preparations	—	1	—	2%
Totals/ranges	284	424	≤0.1%–10%	0.0001%–6%

^aOriginally, Face and Neck and Body and Hand were combined as one category, but now they are separated.

TABLE 10
Glycol Stearate SE

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentrations (Elder 1982)	2001 concentrations (CTFA 2001)
Other bath preparations	—	—	—	0.2%
Other eye makeup preparations	—	2	—	—
Makeup bases	—	—	—	0.9%
Makeup fixatives	—	1	—	—
Other personal cleanliness products	—	—	—	0.2%
Skin cleansing preparations	—	1	—	0.2%
Body and hand skin preparations	—	3	—	—
Moisturizing preparations	—	6	—	—
Paste masks (mud packs)	—	—	—	12%
Other skin care preparations	1	—	>0.1%–1%	—
Suntan gels, creams, and liquids	—	1	—	2%
Other suntan preparations	—	—	—	5%
Totals/ranges	1	14	>0.1%–1%	0.2%–12%

Glycol Stearate SE

There was one formulation reported to the FDA in 1976 that contained Glycol Stearate SE, in the >0.1% to 1% concentration range. In 2001, there were 14 formulations reported to the FDA that contained Glycol Stearate SE, in five new product categories (FDA 2001). Concentration of use data from 2001 was provided (CTFA 2001). Table 10 presents the available use information for Glycol Stearate SE.

Glycol Distearate

There were 26 formulations that contained Glycol Distearate at concentrations from >0.1% to 10% in 1976. In 2001, there were 28 formulations reported to the FDA that contained Glycol Distearate (FDA 2001). Glycol Distearate was reported to be used in three new product categories and no longer used in four categories as compared to the 1976 data. Concentration of use data from 2001 was provided (CTFA 2001).

TABLE 11
Glycol Distearate use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentrations (Elder 1982)	2001 concentrations (CTFA 2001)
Other baby products	—	—	—	1%
Bath oils, tablets, and salts	—	—	—	0.4%
Bubble baths	—	—	—	2%
Other bath preparations	—	1	—	0.7%–3%
Mascara	—	—	—	3%
Hair conditioners	1	1	>0.1%–1%	2%–9%
Permanent waves	5	—	>1%–5%	—
Shampoos (noncoloring)	15	7	>0.1%–5%	—
Other hair preparations	—	1	—	2%
Hair dyes and colors	1	—	>0.1%–1%	0.2%
Other hair coloring preparations	—	—	—	0.5%
Bath soaps and detergents	—	15	—	2%–3%
Deodorants (underarm)	1	—	>1%–5%	—
Other personal cleanliness products	1	—	>5%–10%	0.5%–3%
Other shaving preparation products	1	1	>1%–5%	—
Skin cleansing preparations	1	2	>1%–5%	0.2%–3%
Body and hand skin preparations	—	—	—	6%
Foot powders and sprays	—	—	—	2%
Other skin care preparations	—	—	—	4%
Totals/ranges	26	28	>0.1%–10%	0.2%–9%

Table 11 presents the available use information for Glycol Distearate.

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IMIDAZOLIDINYL UREA

A safety assessment of Imidazolidinyl Urea was published in 1980 with the conclusion that this ingredient is “safe when incorporated in cosmetic products in amounts similar to those presently marketed” (Elder 1980). 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 this safety assessment.

In 1976, Imidazolidinyl Urea was used in 1061 cosmetic products, with the largest single use in face powder products in the concentration range of $\leq 0.1\%$ to 5% . In 2001, there were uses reported in 2025 products, with the largest single use in eye shadow (FDA 2001). In 2001, the maximum use concentration

TABLE 12
Imidazolidinyl Urea use

Product category	1976 use (Elder 1980)	2001 use (FDA 2001)	1976 concentrations (Elder 1980)	2001 concentrations (CTFA 2001)
Baby shampoos	2	1	$\leq 0.1\%$ – 1%	0.5%
Baby lotions, oils, powders, etc.	1	2	$> 0.1\%$ – 1%	0.3%–0.6%
Other baby products	—	1	—	0.3%
Bath oils, tablets, and salts	12	—	$> 0.1\%$ – 1%	0.2%–0.5%
Bubble baths	15	26	$\leq 0.1\%$ – 1%	0.3%–0.4%
Other bath preparations	12	60	$\leq 0.1\%$ – 1%	0.5%
Eyebrow pencil	13	4	$\leq 0.1\%$ – 1%	0.3%
Eyeliners	99	18	$\leq 0.1\%$ – 5%	0.01%–0.6%
Eye shadow	—	301	—	0.2%–0.5%
Eye lotion	—	7	—	0.5%
Eye makeup remover	3	16	$\leq 0.1\%$ – 1%	0.1%–0.5%
Mascara	46	59	$\leq 0.1\%$ – 1%	0.3%–0.5%
Other eye makeup preparations	18	28	$\leq 0.1\%$ – 1%	0.3%–0.5%
Colognes and toilet waters	1	3	$\leq 0.1\%$	0.4%
Perfumes	—	11	—	0.4%–0.5%
Powders	52	19	$\leq 0.1\%$ – 1%	0.2%–0.4%
Sachets	13	—	$\leq 0.1\%$ – 1%	0.1%
Other fragrance preparations	2	17	$\leq 0.1\%$	0.4%–0.5%
Hair conditioners	35	35	$\leq 0.1\%$ – 5%	—
Hair sprays (aerosol fixatives)	—	1	—	0.4%
Permanent waves	1	6	$\leq 0.1\%$ – 1%	—
Rinses (noncoloring)	6	2	$\leq 0.1\%$ – 5%	0.2%
Shampoos (noncoloring)	43	46	$\leq 0.1\%$ – 5%	0.2%–0.5%
Hair tonics, dressings, etc.	8	24	$\leq 0.1\%$ – 1%	0.4%
Wave sets	4	3	$\leq 0.1\%$ – 1%	0.3%
Other hair preparations	4	7	$\leq 0.1\%$ – 1%	0.2%
Hair dyes and colors	—	3	—	—

(Continued on next page)

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

TABLE 12
Imidazolidinyl Urea use (*Continued*)

Product category	1976 use (Elder 1980)	2001 use (FDA 2001)	1976 concentrations (Elder 1980)	2001 concentrations (CTFA 2001)
Hair tints	—	—	—	0.4%
Hair rinses (coloring)	—	1	—	0.2%
Hair bleaches	—	—	—	0.4%
Hair shampoos (coloring)	1	1	>0.1%–1%	—
Other hair-coloring preparations	1	1	≤0.1%	—
Blushers (all types)	54	120	≤0.1%–5%	0.2%–0.4%
Face powders	107	69	≤0.1%–5%	0.2%–0.3%
Foundations	68	98	≤0.1%–5%	0.2%–0.5%
Leg and body paints	1	2	>0.1%–1%	0.2%
Lipstick	5	11	≤0.1%	0.4%
Makeup bases	30	38	≤0.1%–1%	0.3%
Rouges	18	2	≤0.1%–1%	0.3%–0.5%
Makeup fixatives	2	3	≤0.1%–1%	0.3%
Other makeup preparations	7	27	≤0.1%–1%	0.2%–0.5%
Basecoats and undercoats	1	—	≤0.1%–1%	—
Cuticle softeners	10	4	≤0.1%–1%	0.3%
Nail creams and lotions	—	4	—	0.2%
Nail polish and enamel	—	—	—	0.2%–0.5%
Other manicuring preparations	—	2	—	0.2%
Bath soaps and detergents	3	36	≤0.1%	0.4%–0.5%
Deodorants (underarm)	4	4	≤0.1%–1%	0.4%
Feminine deodorants	—	—	—	0.2%
Other personal cleanliness products	1	5	≤0.1%	0.2%–0.3%
Aftershave lotion	—	19	—	0.3%–0.6%
Men's talcum	1	—	>0.1%–1%	—
Shaving cream	1	15	≤0.1%	0.1%–1%
Other shaving preparation products	—	4	—	—
Skin cleansing preparations	71	128	≤0.1%–5%	0.2%–0.6%
Face and neck skin preparations ^a	58	41	≤0.1%–1%	0.3%–0.6%
Body and hand skin preparations ^a	—	157	—	0.3%–0.6%
Foot powders and sprays	1	4	≤0.1%–1%	0.3%–0.4%
Moisturizing preparations ^b	94	215	≤0.1%–5%	0.4%–0.6%
Wrinkle smoothing (removers) ^b	3	—	0.1%–1%	—
Night creams, lotions, etc.	28	60	≤0.1%–5%	0.5%
Paste masks (mud packs)	23	60	≤0.1%–1%	0.3%–0.5%
Skin fresheners	21	35	≤0.1%–1%	0.3%–0.5%
Other skin care preparations	42	124	≤0.1%–1%	0.1%–0.7%
Suntan gels, creams, and liquids	14	15	≤0.1%–1%	0.3%–0.5%
Indoor tanning preparations	—	12	—	0.2%–0.5%
Other suntan preparations	1	8	>0.1%–1%	0.2%–0.5%
Totals/ranges	1061	2025	≤0.1%–5%	0.1%–1%

^aOriginally, Face and Neck and Body and Hand were combined as one category, but now they are separated.

^bWrinkle smoothing (removers) is now part of the Moisturizing category.

was 1% (CTFA 2001). Table 12 presents the available use information for Imidazolidinyl Urea.

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ISOPROPYL LANOLATE

A safety assessment of Isopropyl Lanolate was published in 1980 with the conclusion that this ingredient is “safe as currently used in cosmetic products” (Elder 1980). New studies, along with the updated information below regarding types and concentrations of use, were considered by the CIR Expert Panel. The Panel determined to not reopen this safety assessment.

The CIR Expert Panel did note that a safety assessment of Lanolin itself and eight derivatives were completed in 1980 (Elder 1980) and safety assessments of polyethylene glycol lanolins were published in 1982 (Elder 1982) and 1996 (Andersen 1996). In all cases, the lanolin ingredients were found safe as used in cosmetic formulations.

As with plant-derived cosmetic ingredients, the CIR Expert Panel has a long history of reviewing animal-derived cosmetic ingredients. It is now common to remind manufacturers that cosmetic products containing any animal-derived ingredient should be formulated to limit the presence of pesticide/heavy metal residues as follows: lead ≤ 0.1 ppm; arsenic ≤ 3 ppm; mercury ≤ 1 ppm; total PCB/pesticide contamination ≤ 40 ppm with ≤ 10 ppm for any specific residue (Andersen 1998). Likewise, the Panel has concluded that cosmetic products containing any animal-derived ingredient should be formulated to be free of detectable pathogenic viruses or infectious agents (CIR 1999).

In 1976, Isopropyl Lanolate was used in 1194 cosmetic products, with the largest single use in lipsticks. In 2001, there were 415 reported uses (FDA 2001), again with the largest single use in lipstick products in a concentration range of 2% to 14% (CTFA 2001). Table 13 presents the available use information for Isopropyl Lanolate.

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

TABLE 13
Isopropyl Lanolate use

Product category	1976 use (CIR 1980)	2001 use (FDA 2001)	1976 concentrations (CIR 1980)	2001 concentrations (CTFA 2001)
Baby lotions, oils, powders, etc.	—	1	—	—
Bath oils, tablets, and salts	3	—	>0.1%–1%	—
Other bath preparations	2	1	>0.1%–5%	—
Eyeliner	69	6	>0.1%–25%	4%–6%
Eye shadow	184	11	>0.1%–25%	2%–10%
Eye makeup remover	1	—	>1%–5%	6%
Mascara	5	—	>1%–10%	4%–5%
Other eye makeup preparations	11	24	>1%–25%	3%–8%
Eyebrow pencil	10	—	>1%–5%	—
Other fragrance preparations	4	—	>0.1%–1%	10%
Hair conditioners	4	4	>0.1%–1%	2%
Hair sprays (aerosol fixatives)	2	—	>0.1%–1%	—
Hair tonics, dressings, etc.	2	—	>1%–5%	—
Other hair preparations	1	—	>1%–5%	—
Other hair-coloring preparations	—	—	—	0.4%
Blushers (all types)	84	13	≤0.1%–25%	3%–13%
Face powders	47	13	>0.1%–5%	3%–6%
Foundations	88	32	>0.1%–25%	1%–26%
Lipstick	348	183	≤0.1%–50%	2%–14%
Makeup bases	176	32	≤0.1%–25%	6%
Rouges	11	—	>0.1%–25%	8%
Makeup fixatives	2	—	>0.1%–1%	—
Other makeup preparations	19	13	>0.1%–25%	—
Cuticle softeners	—	2	—	1%–9%
Nail creams and lotions	—	—	—	1%
Other manicuring preparations	—	—	—	1%
Bath soaps and detergents	—	4	—	—
Deodorants (underarm)	2	—	≤0.1%–5%	—
Aftershave lotions	3	6	>1%–5%	1%
Shaving cream	2	3	>0.1%–1%	—
Other shaving preparation products	1	—	>1%–5%	—
Skin cleansing preparations	5	7	>0.1%–10%	4%
Face and neck skin care preparations ^a	48	2	>0.1%–25%	2%–5%
Body and hand skin care preparations ^a	—	22	—	1%–2%
Hormone	1	—	>0.1%–1%	—
Foot powders and sprays	—	1	—	2%
Moisturizing preparations	41	16	≤0.1%–10%	1%–5%
Night creams, lotions, etc.	4	8	>1%–10%	—
Paste masks (mud packs)	—	3	—	2%
Skin lighteners	1	—	>1%–5%	—
Skin fresheners	2	—	>0.1%–5%	—
Wrinkle smoothing (removers)	2	—	>5%–10%	—
Other skin care preparations	4	5	>1%–5%	4%–7%
Suntan gels, creams, and liquids	3	2	≤0.1%–10%	—
Other suntan preparations	2	1	>0.1%–5%	15%
Totals/ranges	1194	415	≤0.1%–50%	0.4%–26%

^aOriginally, Face and Neck and Body and Hand were combined as one category, but now they are separated.

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LITHIUM STEARATE, ALUMINUM DISTEARATE, ALUMINUM STEARATE, ALUMINUM TRISTEARATE, AMMONIUM STEARATE, CALCIUM STEARATE, MAGNESIUM STEARATE, POTASSIUM STEARATE, SODIUM STEARATE, AND ZINC STEARATE

A safety assessment of Lithium Stearate, Aluminum Stearate, Aluminum Distearate, Aluminum Tristearate, Ammonium Stearate, Calcium Stearate, Magnesium Stearate, Potassium Stearate, Sodium Stearate, and Zinc Stearate was published in 1982 with the conclusion that these ingredients “are safe as cosmetic ingredients in the present practices of use and concentration” (Elder 1982). New studies, along with updated information regarding types and concentrations of use, were considered by the CIR Expert Panel. The Panel determined to not reopen this safety assessment.

Lithium Stearate

Lithium Stearate was reported to be used in 98 cosmetic preparations in 1976, with the greatest use occurring in powders and foundations at concentrations that ranged from less than 0.1% to 5%. In 2001, Lithium Stearate was reported to be used in 17 preparations (FDA 2001), but concentration of use data were not given (CTFA 2001). Note that a transposition occurred in the original 1982 published safety assessment and the product information for Lithium Stearate is incorrect in that report. Table 14 presents the available use information with the correct data from 1976.

TABLE 14
Lithium Stearate use

Product category	1976 use ^a	2001 use (FDA 2001)	1976 concentrations (Elder 1982)	2001 concentrations (CTFA 2001)
Eyeliner	—	—	—	2%
Eye shadow	13	—	>0.1%–5%	—
Other eye makeup preparations	—	1	—	—
Powders	28	—	>0.1%–5%	—
Hair tonics, dressings, etc.	—	—	—	3%
Blushers (all types)	1	5	≤0.1%	—
Face powders	2	2	>1%–5%	—
Foundations	27	8	>0.1%–1%	—
Lipstick	1	1	>0.1%–1%	—
Makeup bases	20	—	≤0.1%	—
Rouges	2	—	≤0.1%	—
Makeup fixatives	1	—	≤0.1%	—
Moisturizing preparations	2	—	>0.1%–1%	—
Other skin care preparations	1	—	>0.1%–1%	—
Totals/ranges	98	17	≤0.1%–5%	2%–3%

^aNote that a transposition occurred in the original 1982 published report and the product information for Lithium Stearate is incorrect. This column presents the correct information.

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

TABLE 15
Aluminum Distearate use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentration (Elder 1982)	2001 concentration (CTFA 2001)
Eyeliners	23	—	>1%–5%	3%
Eye shadow	—	17	—	—
Mascara	18	3	>1%–5%	3%
Other eye makeup preparations	—	1	—	—
Hair dyes and colors	—	1	—	—
Hair lighteners with color	—	1	—	3%
Hair bleaches	2	1	>1%–5%	—
Blushers (all types)	—	3	—	—
Face powders	—	3	—	—
Foundations	3	10	>0.1%–1%	0.7%–3%
Lipstick	17	1	>1%–5%	5%
Makeup bases	1	—	>0.1%–1%	—
Other makeup preparations	—	6	—	—
Skin cleansing preparations	2	1	>0.1%–1%	—
Face and neck skin care preparations	—	1	—	—
Moisturizing preparations	1	—	>0.1%–1%	0.1%
Night creams, lotions, etc.	—	1	—	0.5%
Totals/ranges	67	50	>0.1%–5%	0.1%–5%

TABLE 16
Aluminum Stearate use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentration (Elder 1982)	2001 concentration (CTFA 2001)
Bath oils, tablets, and salts	1	—	>1%–5%	—
Eyebrow pencil	—	—	—	0.5%
Eyeliners	14	—	>1%–5%	0.9%–3%
Eye shadow	2	—	>1%–5%	7%
Eye makeup remover	2	—	>1%–5%	4%
Mascara	70	1	>0.1%–5%	1%
Other eye makeup preparations	2	—	>1%–10%	0.7%
Hair tonics, dressings, etc.	4	—	>0.1%–5%	—
Hair bleaches	1	—	>1%–5%	—
Blushers (all types)	10	1	>0.1%–5%	5%
Face powders	—	—	—	4%
Foundations	—	—	—	0.3%–3%
Lipstick	12	—	>0.1%–5%	0.3%–1%
Makeup bases	20	—	>0.1%–5%	—
Other personal cleanliness products	1	—	>0.1%–1%	—
Face and neck skin care preparations	—	1	—	0.3%
Body and hand skin care preparations	—	—	—	0.4%
Moisturizing preparations	—	—	—	0.4%–4%
Paste masks (mud packs)	—	—	—	1%
Suntan gels, creams and liquids	—	—	—	0.4%–8%
Totals/ranges	139	3	>0.1%–10%	0.3%–8%

TABLE 17
Aluminum Tristearate use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentration (Elder 1982)	2001 concentration (CTFA 2001)
Eye lotion	7	—	>0.1%–10%	—
Mascara	—	4	—	—
Hair conditioners	—	1	—	—
Hair tonics, dressings, etc.	—	4	—	—
Makeup bases	1	1	>1%–5%	—
Body and hand creams, etc.	—	1	—	—
Night creams, lotions, etc.	—	1	—	—
Totals/ranges	8	12	>0.1%–10%	—

TABLE 18
Ammonium Stearate use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentration (Elder 1982)	2001 concentration (CTFA 2001)
Hair straighteners	2	—	>0.1%–10%	—
Hair bleaches	1	—	>1%–5%	—
Totals/ranges	3	None	>0.1%–10%	—

TABLE 19
Calcium Stearate use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentration (Elder 1982)	2001 concentration (CTFA 2001)
Eyebrow pencil	12	—	>25%–50%	—
Eyeliner	—	3	—	20%
Eye shadow	—	69	—	0.2%–10%
Mascara	3	—	>0.1%–5%	—
Powders	—	5	—	5%
Other fragrance preparations	—	1	—	—
Hair conditioners	2	—	>1%–10%	—
Other hair preparations	1	—	>0.1%–1%	—
Hair bleaches	1	4	>1%–5%	1%
Blushers (all types)	—	8	—	5%–7%
Face powders	1	7	>10%–25%	0.2%–9%
Foundations	—	3	—	3%
Leg and body paints	—	1	—	—
Lipstick	—	3	—	1%–23%
Makeup bases	—	1	—	—
Rouges	—	1	—	—
Other makeup preparations	2	—	>10%–50%	—
Nail polish and enamel	—	1	—	0.09%
Other manicuring preparations	—	—	—	4%
Deodorants (underarm)	—	—	—	0.02%
Skin-cleansing preparations	—	—	—	0.1%–2%
Suntan gels, creams and liquids	—	—	—	3%
Totals/ranges	23	107	0.1%–50%	0.02%–23%

TABLE 20
Magnesium Stearate use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentrations (Elder 1982)	2001 concentrations (CTFA 2001)
Baby lotions, oils, powders etc.	3	—	>1%–25%	2%
Other bath preparations	1	—	>1%–5%	—
Eyebrow pencil	—	—	—	1%
Eyeliner	2	—	>5%–10%	5%
Eye shadow	57	47	>0.1%–25%	5%
Mascara	1	1	>0.1%–1%	3%
Other eye makeup preparations	—	1	—	3%
Powders	—	8	—	1%
Other fragrance preparations	4	—	>0.1%–1%	—
Shampoos (noncoloring)	2	—	>0.1%–1%	—
Blushers (all types)	9	5	>1%–10%	5%–7%
Face powders	62	12	>1%–10%	5%–8%
Foundations	1	1	>1%–5%	0.5%–3%
Lipstick	—	—	—	1%
Makeup bases	9	1	>1%–5%	0.5%
Other makeup preparations	—	—	—	3%
Other oral hygiene products	—	—	—	1%
Rouges	1	—	>1%–5%	—
Bath soaps and detergents	—	2	—	—
Feminine deodorants	1	3	>0.1%–1%	—
Other personal cleanliness products	4	—	≤0.1%	—
Men's talcum	—	1	—	1%
Preshave lotion (all types)	1	—	>1%–5%	—
Skin cleansing preparations	1	—	>1%–5%	—
Face and neck skin care preparations	4	—	>0.1%–5%	—
Body and hand skin care preparations	—	4	—	0.1%
Foot powders and sprays	—	1	—	—
Moisturizing preparations	—	3	—	3%
Night preparations	—	1	—	—
Paste masks (mud packs)	—	2	—	—
Other skin care preparations	4	1	>0.1%–5%	—
Suntan gels, creams and liquids	—	—	—	0.02%
Indoor tanning preparations	—	2	—	—
Other suntan preparations	—	—	—	0.03%
Totals/ranges	167	96	>0.1%–5%	0.02%–8%

TABLE 21
Potassium Stearate use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentrations (Elder 1982)	2001 concentrations (CTFA 2001)
Foundations	—	—	—	0.05%
Aftershave lotions	—	—	—	0.05%
Face and neck skin care preparations	2	—	>0.1%–25%	—
Skin cleansing preparations	—	—	—	12%
Moisturizing preparations	1	—	>1%–5%	—
Totals/ranges	3	None	0.1%–25%	0.05%–12%

TABLE 22
Sodium Stearate use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentrations (Elder 1982)	2001 concentrations (CTFA 2001)
Baby lotions, oils, powders, etc.	—	2	—	—
Other bath preparations	—	1	—	—
Eyebrow pencil	—	—	—	7%
Eyeliners	—	3	—	8%
Eye shadow	—	1	—	7%
Eye lotion	—	—	—	0.7%
Colognes and toilet water	11	4	>1%–25%	5%
Sachets	1	—	>5%–10%	—
Other fragrance preparations	17	2	>1%–10%	5%–8%
Hair conditioners	1	—	>1%–5%	—
Shampoos (noncoloring)	9	—	>0.1%–25%	—
Hair dyes and colors	—	1	—	—
Hair tints	—	1	—	—
Hair shampoos (coloring)	1	—	>1%–5%	—
Hair lighteners with color	1	1	>1%–5%	12%
Hair bleaches	4	10	>1%–25%	10%
Foundations	—	—	—	3%–6%
Leg and body paints	—	—	—	5%
Lipstick	—	—	—	0.1%
Other hair coloring preparations	—	1	—	—
Blushers (all types)	8	—	>1%–10%	—
Makeup bases	2	1	>10%–25%	—
Other makeup preparations	1	—	>5%–10%	6%–7%
Dentifrices	1	—	>0.1%–1%	—
Bath soaps and detergents	5	29	>1%–5%	17%–18%
Deodorants (underarm)	38	101	>1%–10%	5%–25%
Other personal cleanliness products	4	2	>5%–10%	—
Shaving cream	—	3	—	—
Skin cleansing preparations	3	3	>0.1%–1%	0.3%–14%
Face and neck skin care preparations ^a	3	1	>0.1%–1%	—
Body and hand skin care preparations ^a	—	10	—	—
Moisturizing preparations	6	5	>0.1%–10%	7%
Night creams, lotions, etc.	1	—	>0.1%–1%	—
Other skin care preparations	1	2	>0.1%–1%	0.0001%–0.4%
Other suntan preparations	1	—	>5%–10%	7%
Totals/ranges	119	184	>0.1%–25%	0.0001%–25%

^aOriginally, Face and Neck and Body and Hand were combined as one category, but now they are separated.

Aluminum Distearate

Aluminum Distearate was reported to be used in 67 preparations in 1976, with the largest single use occurring in eyeliner at concentrations of >1% to 5%. In 2001, Aluminum Distearate was reported to be used in 50 cosmetic preparations (FDA 2001). Concentrations ranged from 0.1% to 5% (CTFA 2001). Table 15 presents the available use information.

Aluminum Stearate

Aluminum Stearate was reported to be used in 139 preparations in 1976, with the largest single use occurring in mascara at concentrations of 0.1% to 5%. In 2001, Aluminum Stearate was reported to be used in only three preparations (FDA 2001); although concentrations of use have been provided for many other uses (CTFA 2001). Table 16 presents the available use information.

TABLE 23
Zinc Stearate use

Product category	1976 use	2001 use (FDA 2001)	1976 concentrations (Elder 1982)	2001 concentrations (CTFA 2001)
Baby lotions, oils, powders, etc.	2	2	>1%–50%	0.5%
Bath oils, tablets and salts	—	—	—	3%
Bubble baths	2	2	>1%–5%	—
Eyebrow pencil	19	11	>1%–25%	8%
Eyeliners	36	31	>0.1%–25%	2%–5%
Eye shadow	707	287	>0.1%–25%	2%–16%
Eye makeup remover	1	—	>1%–5%	1%
Mascara	13	5	>0.1%–5%	2%–11%
Other makeup preparations	21	12	>0.1%–25%	2%–12%
Perfumes	1	—	>1%–5%	—
Powders	178	66	>0.1%–10%	2%–10%
Other fragrance preparations	—	—	—	2%
Shampoos (noncoloring)	3	1	>0.1%–5%	—
Blushers (all types)	107	134	>0.1%–25%	0.8%–15%
Face powders	225	168	>1%–25%	2%–24%
Foundations	20	6	>0.1%–10%	2%–10%
Lipstick	2	2	>1%–5%	3%
Makeup bases	11	1	>0.1%–5%	1%
Rouges	23	2	>0.1%–25%	5%
Other makeup preparations	1	3	>0.1%–1%	2%–5%
Deodorants (underarm)	1	—	>10%–25%	2%
Feminine deodorants	1	—	>0.1%–1%	—
Other personal cleanliness products	3	—	>1%–10%	—
Men's talcum	5	2	>1%–10%	—
Preshave lotions (all types)	1	—	>1%–5%	—
Skin cleansing preparations	2	1	>0.1%–10%	1%
Face and body skin care preparations ^a	6	—	>1%–25%	—
Body and hand skin care preparations ^a	—	3	—	1%
Foot powders and sprays	2	2	>1%–5%	2%
Moisturizing preparations	3	—	>0.1%–5%	1%
Night preparations	1	2	>10%–25%	2%
Other skin care preparations	—	3	—	51%
Totals/ranges	1397	746	>0.1%–50%	0.5%–51%

^aOriginally, Face and Neck and Body and Hand were combined as one category, but now they are separated.

Aluminum Tristearate

Aluminum Tristearate was reported to be used in eight preparations; concentrations ranged from 0.1% to 10%. In 2001, Aluminum Tristearate was reported to be used in 12 preparations (FDA 2001), but concentrations of use were not given (CTFA 2001). Table 17 presents the available use information.

Ammonium Stearate

Ammonium Stearate was reported to be used in only three cosmetic products in 1976; concentrations ranged from 0.1% to 10%. In 2001, Ammonium Stearate was not reported to be

used in cosmetic preparations (FDA 2001; CTFA 2001). Table 18 presents the available use information.

Calcium Stearate

Calcium Stearate was reported to be used in 23 preparations in 1976, with the largest single use occurring in eyebrow pencils; concentrations ranged from >25% to 50%. In 2001, Calcium Stearate was reportedly used in 107 cosmetic preparations (FDA 2001), with the largest single use occurring in eye shadow at concentrations that range from 0.2% to 10% (CTFA 2001). Concentrations of use were given for several product categories in which no uses had been reported in 2001. Table 19 presents the available use information.

Magnesium Stearate

Magnesium Stearate was reported to be used in 167 preparations in 1976, with the greatest use occurring in eye shadows and face powders; concentrations ranged from 0.1% to 25%. In 2001, Magnesium Stearate was reportedly used in 96 preparations (FDA 2001); concentrations ranged from 0.02% to 8% (CTFA 2001). Table 20 presents the available use information.

Potassium Stearate

Potassium Stearate was reported to be used in three cosmetic preparations in 1976, at concentrations from 0.1% to 25%. No uses were reported to FDA in 2001 (FDA 2001), but use concentrations were provided in several product categories (CTFA 2001). Table 21 presents the available use information.

Sodium Stearate

Sodium Stearate was reported to be used in 119 preparations in 1976, with the largest single use occurring in deodorants; concentrations ranged from > 1% to 10%. In 2001, Sodium Stearate was reportedly used in 184 preparations (FDA 2001); a maximum concentration of 25% was given for deodorants (CTFA 2001). Table 22 presents the available use information.

Zinc Stearate

Zinc Stearate was reported to be used in 1397 cosmetic preparations in 1976, with the largest use occurring in eye shadow.

Concentrations ranged from >0.1% to 50%. In 2001, Zinc Stearate was reportedly used in 746 cosmetic preparations (FDA 2001); concentrations range from 0.5% to 51% (CTFA 2001). Note that a transposition occurred in the original 1982 published safety assessment and the product information for Zinc Stearate is incorrect in that report. Table 23 presents the available use information with the correct data from 1976.

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TABLE 24
Quaternium-18 use

Product category (FDA 2001)	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentration (Elder 1982)	2001 concentration (CTFA 2001)
Other eye makeup preparations	—	1	—	—
Hair conditioners	5	52	> 1%–10%	2%
Hair sprays (aerosol fixatives)	—	1	—	—
Permanent waves	—	1	—	—
Rinses (noncoloring)	4	7	>0.1%–1%	1%
Shampoos (noncoloring)	—	1	—	—
Hair tonics, dressings, etc.	—	2	—	0.1%–2%
Other hair preparations	—	4	—	0.8%
Hair bleaches	—	1	—	—
Foundations	—	11	—	—
Lipstick	—	—	—	0.7%
Basecoats and undercoats	—	2	—	—
Nail polish and enamel	11	2	>0.1%–1%	—
Other manicuring preparations	—	1	—	—
Other personal cleanliness products	—	1	—	—
Moisturizing preparations	—	1	—	—
Other skin care preparations	—	2	—	—
Totals/ranges	20	90	>0.1%–10%	0.1%–2%

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

TABLE 25
Quaternium-18 Bentonite

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentration (Elder 1982)	2001 concentration (CTFA 2001)
Eyebrow pencil	—	10	—	—
Eyeliner	—	42	—	5%
Eye shadow	—	13	—	—
Eye lotion	—	—	—	6%
Mascara	—	4	—	4%–9%
Other eye makeup preparations	—	1	—	—
Blushers	—	—	—	0.8%
Lipstick	1	138	>5%–10%	5%
Makeup bases	—	1	—	—
Other makeup preparations	—	8	—	—
Other personal cleanliness products	7	3	>0.1%–1%	—
Moisturizing preparations	—	1	—	—
Skin fresheners	—	—	—	5%
Totals/ranges	8	221	>0.1%–10%	0.8%–9%

TABLE 26
Quaternium-18 Hectorite use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentration (Elder 1982)	2001 concentration (CTFA 2001)
Bath oils, tablets, and salts	—	—	—	3%
Eyeliner	—	12	—	2%–4%
Eye shadow	17	11	>0.1%–10%	0.2%–6%
Eye makeup remover	—	3	—	—
Mascara	12	19	≤0.1%–5%	0.5%–13%
Other eye makeup preparations	1	8	>1%–5%	12%
Perfumes	—	1	—	—
Other fragrance preparations	—	—	—	4%
Hair straighteners	—	2	—	—
Other hair-coloring preparations	—	1	—	—
Blushers	5	—	>0.1%–10%	—
Face powders	1	—	>0.1%–1%	2%
Foundations	1	15	>0.1%–1%	0.8%–8%
Leg and body paints	—	—	—	1%
Lipstick	8	25	>0.1%–5%	0.9%–8%
Makeup bases	2	10	>0.1%–5%	0.9%–3%
Rouges	6	1	≤0.1%–5%	—
Makeup fixatives	—	2	—	—
Other makeup preparations	2	14	>1%–10%	0.5%–2%
Nail polish and enamel	82	1	≤0.1%–5%	—
Deodorants (underarm)	—	4	—	0.5%–5%
Other personal cleanliness products	4	26	>0.1%–1%	19%
Skin cleansing preparations	—	2	—	—
Face and neck skin care preparations	—	3	—	2%
Moisturizing preparations	—	3	—	0.07%–1%
Night preparations	—	5	—	—
Paste masks (mud packs)	—	1	—	—
Other skin care preps	—	4	—	4%
Suntan gels, creams, and liquids	1	3	>5%–10%	1%
Other suntan preparations	—	—	—	0.5%
Totals/ranges	142	176	≤0.1%–10%	0.07%–19%

QUATERNIUM-18, QUATERNIUM-18 HECTORITE, AND QUATERNIUM-18 BENTONITE

A safety assessment of Quaternium-18, Quaternium-18 Hectorite, and Quaternium-18 Bentonite was published in 1982 with the conclusion that these ingredients are “safe as cosmetic ingredients in the present practices of use and concentration” (Elder 1982). New studies, along with updated information below regarding uses and use concentrations, were considered by the CIR Expert Panel. The Panel determined to not reopen this safety assessment.

Quaternium-18

Quaternium-18 is now reportedly used in hair sprays. The effects of inhaled aerosols depend on the specific chemical species, the concentration, the duration of exposure, and site of deposition within the respiratory system. Particle size is the most important factor affecting the location of deposition (Jensen and O'Brien 1993). The mean aerodynamic diameter of pump hair spray particles is $\geq 80 \mu$, and the diameter of anhydrous hair spray particles is 60 to 80μ . Typically less than 1% are below 10μ , which is the upper limit for respirable particles (Bower 1999). Based on the particle size, Quaternium-18 would not be respirable in formulation.

Quaternium-18 was used in a total of 20 cosmetic products in 1976, with the largest single use in nail polish and enamel products at concentrations up to 1%. In 2001, Quaternium-18 was reportedly used in 90 cosmetic products (FDA 2001), with the largest single use in hair conditioners at a 2% concentration (CTFA 2001). Table 24 presents the available use information on Quaternium-18.

Quaternium-18 Bentonite

Quaternium-18 Bentonite was used in eight products in 1976, with the largest single use in other personal cleanliness preparations at concentrations up to 1%. In 2001, Quaternium-18 Bentonite was reportedly used in 221 products (FDA 2001), with the largest single use in lipsticks at concentrations up to 5% (CTFA 2001). Table 25 presents the available use information on Quaternium-18 Bentonite.

Quaternium-18 Hectorite

Quaternium-18 Hectorite was used in 142 products in 1976, with the largest single use in nail polish and enamel products at concentrations up to 5%. In 2001, Quaternium-18 Hectorite was used in 176 products (FDA 2001), with the largest single use in other personal cleanliness products at concentrations up to 19% (CTFA 2001). Table 26 presents the available use information on Quaternium-18 Hectorite.

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SQUALENE AND SQUALANE

A safety assessment of Squalene and Squalane was published in 1982 with the conclusion that these ingredients are “safe as cosmetic ingredients in the present practices of use and concentration” (Elder 1982). New studies, along with updated information regarding types and concentrations of use, were considered by the CIR Expert Panel. The Panel determined to not reopen this safety assessment.

Squalene

Squalene was used in 18 cosmetic products in 1976, with the largest use occurring in moisturizing preparations at concentrations of $\leq 10\%$. In 2001, Squalene was used in 29 products (FDA 2001), at a maximum use concentration of 10% in face powders (CTFA 2001). Table 27 presents the available use information for Squalene.

Squalane

Squalane was used in 400 products in 1976, with the largest use occurring in moisturizing preparations at concentrations of

TABLE 27
Squalene use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentrations (Elder 1982)	2001 concentrations (CTFA 2001)
Bath oils, tablets, and salts	—	1	—	—
Other bath preparations	1	—	>0.1%–1%	0.2%
Eyebrow pencil	—	—	—	0.7%
Eyeliner	—	—	—	0.7%
Eye shadow	—	—	—	0.5%
Eye makeup remover	1	—	>1%–5%	—
Shampoos (noncoloring)	—	—	—	0.01%
Blushers (all types)	1	—	>25%–50%	0.5%
Face powders	—	—	—	10%
Foundations	1	2	>0.1%–1%	2%
Lipstick	—	—	—	0.7%
Other makeup preparations	—	—	—	0.02%
Bath soaps and detergents	—	—	—	0.2%
Skin cleansing preparations	—	2	—	0.5%
Face and neck skin care preparations ^a	3	6	≤0.1	0.5%
Body and hand skin care preparations ^a	—	6	—	0.08%–0.5%
Foot powders and sprays	—	1	—	—
Moisturizing preparations ^b	6	7	≤10%	0.06%–0.5%
Wrinkle smoothing (removers) ^b	1	—	≤1%	—
Night preparations	1	2	>1%–5%	0.5%
Paste mask (mud packs)	—	—	—	0.5%
Skin fresheners	1	—	≤1%	—
Other skin care preparations	1	2	≤5%	0.5%
Suntan gels, creams, and liquids	1	—	>0.1%–1%	0.02%–0.3%
Other suntan preparations	—	—	—	0.2%
Totals/ranges	18	29	≤1% to 50%	0.02%–10%

^aOriginally, Face and Neck and Body and Hand were combined as one category, but now they are separated.

^bWrinkle smoothing (removers) was added to the Moisturizing category.

TABLE 28
Squalane use

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentrations (Elder 1982)	2001 concentrations (CTFA 2001)
Baby lotions, oils, powders, etc.	2	2	>0.1%–1%	—
Bath oils, tablets, and salts	9	—	>0.1%–10%	—
Other bath preparations	1	—	≤0.1	—
Eyebrow pencil	—	—	—	2%
Eyeliner	7	—	>0.1%–5%	2%
Eye shadow	8	30	>0.1%–25%	10%
Eye lotion	—	5	—	3%
Eye makeup remover	2	1	>0.1%–5%	5%
Mascara	3	—	>1%–10%	0.01%
Other eye makeup preparations	—	6	—	10%–15%
Perfumes	2	2	>1%–5%	—
Powders	1	2	>0.1%–1%	3%
Other fragrance preparations	1	8	>5%–10%	—
Hair conditioners	4	9	>0.1%–5%	5%

(Continued on next page)

TABLE 28
Squalane use (*Continued*)

Product category	1976 use (Elder 1982)	2001 use (FDA 2001)	1976 concentrations (Elder 1982)	2001 concentrations (CTFA 2001)
Hair sprays (aerosol fixatives)	4	2	≤1%	—
Hair straighteners	—	4	—	—
Permanent waves	15	—	>0.1%–1%	—
Rinses (noncoloring)	1	—	>0.1%–1%	0.8%
Shampoos (noncoloring)	2	—	≤1%	—
Tonics, dressings, and other hair grooming aids	—	1	—	—
Other hair preparations	1	1	>1%–5%	—
Blushers (all types)	13	13	≤25	10%
Face powders	12	26	>0.1%–1%	9%
Foundations	7	50	≤10%	3%–31%
Lipstick	2	62	>10%–50%	3%–17%
Makeup bases	19	12	>0.1%	5%
Rouges	5	—	>1%–10%	—
Makeup fixatives	—	1	—	—
Other makeup preparations	11	12	>1%–25%	6%–30%
Cuticle softeners	1	2	>5%–10%	—
Nail creams and lotions	1	1	>10%–25%	—
Nail polish and enamel removers	1	1	>1%–5%	—
Other manicuring preparations	1	2	>0.1%–1%	—
Bath soaps and detergents	—	—	—	0.1%–1%
Deodorants (underarm)	—	—	—	3%
Other personal cleanliness products	4	1	>0.1%–10%	—
Aftershave lotions	—	3	—	2%
Shaving cream	—	2	—	0.1%–1%
Skin cleansing preparations	—	21	—	2%–5%
Face and neck skin care preparations ^a	13	15	>0.1%–50%	3%–97%
Body and hand skin care preparations ^a	13	51	>0.1%–50%	0.1%–4%
Foot powders and sprays	1	2	>0.1%–1%	—
Moisturizing preparations	71	128	≤25%	2%–36%
Night preparations	29	28	>0.1%–50%	5%–6%
Paste mask (mud packs)	3	15	≤10%	1%–4%
Skin lighteners	3	—	>0.1%–5%	—
Skin fresheners	2	—	≤0.1%	—
Wrinkle smoothing (removers)	2	—	≤5%	—
Other skin care preparations	16	61	>0.1%–25%	3%–10%
Suntan gels, creams, and liquids	5	8	>0.1%–25%	0.3%
Indoor tanning preparations	1	2	>1%–5%	—
Other suntan preparations	—	3	—	—
Totals/ranges	400	595	≤0.1%–50%	0.01%–97%

^aOriginally, Face and Neck and Body and Hand were combined as one category, but now they are separated.

≤25%. In 2001, Squalane was used in 595 products (FDA 2001), at use concentration up to 97% reported for face and neck skin care preparations (CTFA 2001). Table 28 presents the available use information for Squalane.

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

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%

^aOriginally, Face and Neck and Body and Hand were combined as one category, but now they are separated.

^bNo longer a product category.

^cWrinkle smoothing (removers) are now part of the Moisturizing category.

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ilar 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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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 sim-

²Available 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%

TABLE 33
Triticum Vulgare (Wheat) Germ Oil

Product category (FDA 2001)	1976 use (Elder 1980c)	2001 use (FDA 2001)	1976 concentrations (Elder 1980c)	2001 concentrations (CTFA 2001)
Bath oils, tablets, and salts	2	—	>0.1%–5%	0.5%
Baby lotions, oils, powders, etc.	—	1	—	—
Bubble bath	1	—	≤0.1%	0.01%
Other bath preparations	—	1	—	0.001%–2%
Eyeline	—	—	—	0.1%
Eye shadow	—	—	—	0.1%–3%
Eye lotion	2	—	≤0.1%–1%	0.2%–0.5%
Eye makeup remover	1	1	≤0.1%	—
Mascara	1	4	≤0.1%	0.5%
Other eye makeup preparations	—	4	—	0.00004%–0.5%
Colognes and toilet waters	—	—	—	0.01%
Hair Conditioner	7	26	≤0.1%–5%	0.0001%–1%
Hair Sprays (aerosol fixatives)	1	2	≤0.1	0.0002%–0.001%
Shampoos (noncoloring)	8	15	≤0.1%–1%	0.0001%–1%
Tonics, dressings, and other hair-grooming aids	—	19	—	0.001%–2%
Wave sets	4	—	≤0.1	0.0025%
Other hair preparations (noncoloring)	—	1	—	0.001%
Hair dyes and colors	—	7	—	0.1%
Hair shampoos (coloring)	1	—	≤0.1	—
Hair bleaches	—	5	—	—
Foundations	1	—	>0.1%–1%	—
Lipstick	21	33	≤0.1%–5%	0.1%–3%
Rouges	6	—	≤0.1%–1%	0.00005%
Other makeup preparations	—	—	—	0.5%–4%
Cuticle softeners	—	—	—	0.1%
Nail creams and lotions	1	2	>10%–15%	4%
Nail polish and enamel removers	1	2	>1%–5%	—
Bath soaps and detergents	—	3	—	0.02–1%
Deodorants	—	—	—	0.02%
Aftershave lotions	—	—	—	0.006%–2%
Beard Softeners	—	—	—	0.01%
Shaving cream (aerosol, brushless, and lather)	1	—	≤0.1%	0.006%
Other shaving preparations	1	1	>1%–5%	—
Skin cleansing preparations	8	13	≤0.1%–5%	0.00002%–5%
Depilatories	—	1	—	—
Face and neck skin care preparations ^a	5	19	>0.1%–5%	0.2%–10%
Body and hand skin care preparations ^a	—	31	—	0.001%–18%
Moisturizing preparations	17	37	≤0.1%–50%	0.001%–5%
Night preparations	5	14	≤0.1%–5%	0.5%–5%
Paste masks (mud packs)	1	8	>1%–5%	0.2%–2%
Skin fresheners	1	1	>1%–5%	8%
Other skin preparations	7	39	≤0.1%–25%	0.001%–1%
Suntan gels, creams, and liquids	4	7	>0.1%–5%	0.03%
Indoor tanning preparations	—	—	—	0.05%
Other suntan preparations	1	6	>0.1%–1%	—
Totals/ranges	113	303	≤0.1%–50%	0.00002%–18%

^aFace and body skin care preparations were originally in the same category.

The Panel noted that a long history of reviewing plant-derived or “botanical” cosmetic ingredients has developed since these ingredients were first considered. As a result of that experience, it is now common to remind manufacturers that cosmetic products containing plant-derived ingredients should be formulated to limit the presence of pesticide/heavy metal residues as follows: lead ≤ 0.1 ppm; arsenic ≤ 3 ppm; mercury ≤ 1 ppm; total PCB/pesticide contamination ≤ 40 ppm, with ≤ 10 ppm for any specific residue (Andersen 1998).

The terminology for several of these ingredients in the *International Cosmetic Ingredient Dictionary and Handbook* has changed (Pepe, Wenninger, and McEwen 2002). Wheat Gluten is currently Triticum Vulgare (Wheat) Gluten. Wheat Flour is Triticum Vulgare (Wheat) Kernel Flour. Wheat Starch is Triticum Vulgare (Wheat) Starch. Wheat Germ Oil is Triticum Vulgare (Wheat) Germ Oil. The nomenclature for Wheat Germ Glycerides has not changed.

Wheat Germ Glycerides

Wheat Germ Glycerides were used in 212 formulations in 1976, primarily in lipsticks at concentrations up to 5%. In 2001, it was used in 128 products, 126 of which were lipsticks (FDA 2001), at concentrations up to 25% (CTFA 2001). Table 30 presents the available use information.

Triticum Vulgare (Wheat) Gluten

Triticum Vulgare (Wheat) Gluten was used in five formulations in 2001 (FDA 2001), as compared to one in 1976. No information on current use concentrations is given (CTFA 2001). Table 31 presents the available use information.

Triticum Vulgare (Wheat) Kernal Flour

Triticum Vulgare (Wheat) Kernal Flour was used in one formulation in 1976, in the concentration range of $>0.1\%$ to 1% . It was not reported to be used in cosmetics in 2001 (FDA 2001; CTFA 2001). No table is provided.

Triticum Vulgare (Wheat) Starch

Triticum Vulgare (Wheat) Starch was used in 39 formulations in 2001 (FDA 2001), as compared to 4 in 1976. Concentrations of use in 2001 (CTFA 2001) were at a maximum of 25%, the same as in 1976. Table 32 presents the available use information for Triticum Vulgare (Wheat) Starch.

Triticum Vulgare (Wheat) Germ Oil

Triticum Vulgare (Wheat) Germ Oil was reportedly used in 303 formulations in 2001 (FDA 2001), as compared to 113 in 1976. In 2001, the maximum concentration of use was 18% (CTFA 2001) compared to 50% in 1976. Table 33 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.

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