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Annual Review of Cosmetic Ingredient Safety Assessments: 2005/2006[1]

The Cosmetic Ingredient Review (CIR) program Expert Panel has assessed the safety of over 1300 cosmetic ingredients since its inception in 1976. These safety assessments were published in the *Journal of Environmental Pathology and Toxicology* in 1980, the *Journal of the American College of Toxicology*, from 1982 to 1996, and since then in the *International Journal of Toxicology*.

Because information relevant to the safety of ingredients may have become available since early safety assessments were published, the CIR Expert Panel has initiated a re-review process to uncover such new data.

In some cases, newly available data are largely redundant with the data available in the original safety assessment. In other cases, new data present new safety issues. If after considering the newly available information, the CIR Expert Panel decides to not 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.

A reference list is provided that updates the available published literature and includes any unpublished data made available since the original safety assessment.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 reconsidered in 2005/2006, and determined not to reopen are:

4-Amino-2-Hydroxytoluene
m, o, and p-Aminophenol
Arachidyl Propionate
Benzalkonium Chloride
Cetearyl, Cetyl, Isostearyl, Myristyl, and Behenyl Alcohol
Diazolidinyl Urea
Disperse Black 9
DMDM Hydantoin
Ethyl Acetate and Butyl Acetate
Methylene Chloride
2-Methyl-5-Hydroxyethylaminophenol
2-Methylresorcinol and Resorcinol
Petroleum Distillate
Phenethyl Alcohol
Polyquaternium-10
Retinyl Palmitate and Retinol
Sodium Cocoamphoacetate, Sodium Cocoamphopropionate, Disodium Cocoamphodiacetate and Disodium Cocoamphodipropionate
Sorbic Acid and Potassium Sorbate
Steareth-2,4,6,7,10,13,15, and -20
Tallow, Tallow Glyceride, Tallow Glycerides, Hydrogenated Tallow Glyceride, and Hydrogenated Tallow Glycerides

Among these are several cosmetic ingredients used in hair dye products (4-Amino-2-Hydroxytoluene; m, o, and p-Aminophenol; Disperse Black 9; 2-Methyl-5-Hydroxyethylaminophenol; 2-Methylresorcinol; and Resorcinol). Hair dyes may be broadly grouped into oxidative (permanent) and direct (semipermanent) hair dyes. The oxidative dyes consist of precursors mixed with developers to produce color, whereas direct hair dyes are a preformed color.

Although the safety of individual hair dye ingredients are not addressed in epidemiology studies that seek to determine links, if any, between hair dye use and disease, such studies do provide broad information and have been considered by the CIR Expert Panel.

In 1993, an International Agency for Research on Cancer (IARC) working group evaluated 78 epidemiology literature citations and concluded that "personal use of hair colourants cannot be evaluated as to its carcinogenicity" and that "occupation as a hairdresser or barber entails exposures that are probably carcinogenic" (IARC 1993). The IARC report did not distinguish between personal use of oxidative/permanent versus direct hair dyes, or distinguish among the multiple chemical exposures in addition to hair dyes to which a hairdresser or barber might be exposed.

Rollison et al. (2006) reviewed the available epidemiology literature published since 1992. The authors found that hair dye exposure assessment ranged from ever/never use to information on type, color, and duration and frequency of use. The authors found insufficient evidence to support a causal association

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between personal hair dye use and a variety of tumors and cancers. The review highlighted well-designed studies with an exposure assessment that included hair dye type, color, and frequency or duration of use, which found associations between personal hair dye use and development of acute leukemia, bladder cancer, multiple myeloma, and non-Hodgkin's lymphoma. These findings, however, were not consistently observed across studies.

The CIR Expert Panel did specifically note reports from a case-control study (Gago-Dominguez et al. 2001, 2003), which did suggest a possible genetically susceptible subgroup, which detoxify arylamines to a lower degree than the general population. The study authors hypothesized that this subgroup may be at greater risk of bladder cancer from hair dye exposure. Rollison et al. (2006) noted that these results were based on small sample sizes.

Several studies published since 2003 also have been considered. Discussion of the available hair dye epidemiology data is also available at http://www.cir-safety.org/findings.shtml.

Hair Dye Epidemiology

Bladder Cancer

Andrew et al. (2004) reported a case-control study of New Hampshire residents whose bladder cancers were entered into a state registry from 1994 to 1998. A follow-up study by Kelsey et al. (2005) examined the links between those bladder cancer cases with an inactivated tumor suppressor gene (TP53) and various exposures. Huncharek and Kupelnick (2005) performed a meta-analysis of six case-control and one cohort study. Takkouche et al. (2005) performed a meta-analysis of the Andrew et al. (2004) study and nine other personal use case-control or cohort studies. Ji et al. (2005) reported a cohort occupational study not included in the above meta-analyses. Kogevinas et al. (2006) presented evidence from a case-control study in Spain. Lin et al. (2006) presented a case-control study of personal permanent hair dye use. Serretta et al. (2006) reported preliminary results from a multicentric study.

Lymphoma and Leukemia

Rauscher et al. (2004) reported a U.S./Canadian case-contol study of adult acute leukemia. Zhang et al. (2004) and Zheng et al. (2004) examined the relationship of hair dye use or diet with non-Hodgkin's lymphoma in a case-control study in Connecticut. Takkouche et al. (2005) reported a meta-analysis of reports of hematopoietic cancers, including that by Rauscher et al. (2004) and Zhang et al. (2004) and 17 other studies. Mester et al. (2005) reviewed 10 epidemiology studies regarding the relationship between occupational exposure in hairdressing and diseases of the malignant lymphoma group. A case-control study in Spain by Benavente et al. (2005) examined the association between lifetime hair dye exposure with various lymphomas, including chronic lymphocytic leukemia. de Sanjosé et al. (2006) reported on the association between personal use of hair dyes and lymphoid neoplasm using data from a European multicenter case-control study.

Other Cancers

Takkouche et al. (2005) included breast cancer and childhood cancers in their meta-analysis. Efird et al. (2005) studied the association between the use of hair-coloring agents the month before or during pregnancy with childhood brain tumors in 1218 cases between 1976 and 1994. Heineman et al. (2005) studied 112 women in Nebraska newly diagnosed with brain cancer (glioma). McCall et al. (2005) reported on the relationship between childhood neuroblastomas and maternal hair dye use in 538 children born between 1992 and 1994 in the United States and Canada.

Other Diseases

Park et al. (2005) reported an occupational case-control study of neurodegenerative diseases, including Alzheimer's disease, presenile dementia and motor neuron disease.

In considering all these data, the CIR Expert Panel concluded that the available epidemiology studies are insufficient to conclude there is a causal relationship between hair dye use and cancer and other end points. The Expert Panel also stated that use of direct hair dyes, although not the focus in all investigations, appears to have little evidence of an association with adverse events as reported in epidemiology studies. However, direct hair dyes are a diverse group of chemicals and the determination of safety may hinge on other safety test data.

The Panel recognizes that hair dye epidemiology studies do not address the safety of individual hair dyes, but is concerned that studies have demonstrated an association between use of oxidative/permanent hair dyes and some cancer endpoints. The Panel, therefore, strongly supports the need to replicate these studies, along with further studies to examine the possibility of susceptible subpopulations.

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4-Amino-2-Hydroxytoluene

CONCLUSION

In its original safety assessment of 4-Amino-2-Hydroxytoluene (Elder 1989), the Cosmetic Ingredient Review (CIR) Expert Panel stated that this ingredient was safe as used in cosmetic products. The Expert Panel considered newly available studies since that assessment, along with updated information regarding types and concentrations of use. The Panel confirmed the safety of 4-Amino-2-Hydroxytoluene in the practices of use and concentrations as given in Table 1, and did not reopen the safety assessment.

DISCUSSION

4-Amino-2-Hydroxytoluene is a component in oxidative hair dyes used in 960 hair-coloring products in 1986, based on voluntary reports submitted to the Food and Drug Administration (FDA) by industry, with concentrations of use ranging from ≤0.1% to 5% (Elder 1989). In 2006, 4-Amino-2-Hydroxytoluene was reportedly used in 641 cosmetic products (FDA 2006). Data from an industry survey in 2006 indicated that 4-Amino-2-Hydroxytoluene was used at concentrations ranging from 0.2% to 2% (CTFA 2006). The available usage and use concentration data are given in Table 1 as a function of product category.

The Panel noted that new mutagenesis data were available, but determined that these data indicate a weak mutagenicity potential.

The CIR Expert Panel has concluded that the available epidemiology studies are insufficient to conclude there is a causal relationship between hair dye use and cancer and other end points; see Hair Dye Epidemiology for a discussion and list of references. A presentation of the available hair dye epidemiology data is available at http://www.cir-safety.org/findings.shtml.

The Expert Panel recognizes that 4-Amino-2-Hydroxytoluene is used as a hair dye ingredient and may be a sensitizer.

TABLE 1
Current and historical uses and concentrations of 4-Amino-2-Hydroxytoluene in cosmetics

Product category	1986 ingredient uses (Elder 1989)	2006 ingredient uses (FDA 2006)	1986 concentrations (Elder 1989) (%)	2006 concentrations (CTFA 2006) (%)
Hair dyes and colors	960[a]	628	≤ 0.1 – 5[a]	0.2–2
Tints	—	12	—	—
Lighteners with color	—	1	—	—
Total uses/ranges for 4-Amino-2-Hydroxytoluene	960	641	≤ 0.1–5	0.2–2

[a]In 1986, separate listings for tints and lighteners were not provided; all uses in this category were listed as hair dyes and colors.

However, hair dyes containing this ingredient, as coal tar hair products, are exempt from the principle adulteration provision and from the color additive provisions in sections 601 and 706 of the Federal Food, Drug, and Cosmetic Act, when the label bears a caution statement and patch test instructions for determining whether the product causes skin irritation. The Expert Panel expects that following this procedure will identify prospective individuals who have had an irritation/sensitization reaction and allow them to avoid significant exposure.

The Panel also is aware that the National Toxicology Program (NTP) has an evaluation scheduled for this ingredient. When information from the NTP is available this ingredient again will be re-reviewed.

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m-, o- and p-Aminophenol

CONCLUSION

In its original safety assessment of m-, o- and p- Aminophenol (Elder 1988), the Cosmetic Ingredient Review (CIR) Expert Panel stated that these ingredients were safe as used in cosmetic products. The Expert Panel considered newly available studies since that assessment, along with updated information regarding types and concentrations of use. The Panel confirmed the safety of m-, o- and p- Aminophenol in the practices of use and concentrations, as given in Table 2, and did not reopen the safety assessment.

DISCUSSION

m-, o-, and p-Aminophenol are components in oxidative hair dyes used in 278, 75, and 402 hair-coloring products in 1981, based on voluntary reports submitted to FDA by industry, with concentrations of use ranging from ≤0.1% to 5%, ≤0.1% to 5%, and ≤0.1% to 5%, respectively (Elder 1988). In 2002, m-, o-, and p-Aminophenol were reportedly used in 855, 89, and 1024 cosmetic products, respectively (FDA 2002). Data from an industry survey in 2005 indicated that m-, o-, and p-Aminophenol were used at concentrations ranging from 0.2% to 2%, 0.2% to 2%, and 0.3% to 0.9%, respectively (CTFA 2005). The available usage and use concentration data are given in Table 2 as a function of product category.

The Panel noted that the discussion in the original review explained that there were likely sufficient endogenous stores of glutathione to inactivate potentially genotoxic aminophenol metabolites. Among the additional studies reviewed by the Panel, however, were several in which glutathione conjugates produced by the reaction with aminophenols was nephrotoxic at high doses. Because of the short duration of contact with these oxidative hair dyes and the time needed for diffusion across the stratum corneum, the actual concentration of aminophenols in the skin is low relative to the amount in the hair dye product. Because the level in the hair dye product is already low, the Panel does not consider it likely that glutathione conjugates could reach nephrotoxic levels.

The CIR Expert Panel has concluded that the available epidemiology studies are insufficient to conclude there is a causal

TABLE 2
Current and historical uses and concentrations of m-, o-, and p-Aminophenol in cosmetic products

Product category	1981 ingredient uses (Elder 1988)	2002 ingredient uses (FDA 2002)	1981 concentrations (Elder 1988) (%)	2005 concentrations (CTFA 2005) (%)
		m-Aminophenol		
Hair dyes and colors	276	846	< 0.1–5	0.2–2%
Hair tints	2	7	≤ 0.1	—
Hair colors sprays (aerosol)	—	1	—	—
Basecoats and undercoats	—	1	—	—
Total uses/ranges for m-Aminophenol	278	855	≤ 0.1–5	0.2–2%
		o-Aminophenol		
Hair dyes and colors	65	88	< 0.1–1	0.7–2%
Hair tints	10	1	≤ 0.1	—
Hair rinses (coloring)	—	—	—	0.2%
Total uses/ranges for o-Aminophenol	75	89	≤ 0.1–1	0.2–2%
		p-Aminophenol		
Hair dyes and colors	396	1015	< 0.1–1	0.3–0.9%
Hair tints	6	8	≤ 0.1	—
Hair colors sprays (aerosol)	—	1	—	—
Total uses/ranges of p-Aminophenol	402	1024	≤ 0.1–1	0.3–0.9%

relationship between hair dye use and cancer and other end points endpoints - see introduction for a discussion and list of references. A discussion of the available hair dye epidemiology data is available at http://www.cir-safety.org/findings.shtml.

The Expert Panel recognizes that m-, o-, and p-Aminophenol may be sensitizers. However, hair dyes containing these ingredients, as coal tar hair products, are exempt from the principle adulteration provision and from the color additive provisions in sections 601 and 706 of the Federal Food, Drug, and Cosmetic Act, when the label bears a caution statement and patch test instructions for determining whether the product causes skin irritation. The Expert Panel expects that following this procedure will identify prospective individuals who have had an irritation/sensitization reaction and allow them to avoid significant exposure.

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Arachidyl Propionate

CONCLUSION

In a safety assessment of Arachidyl Propionate (Elder 1990), the Cosmetic Ingredient Review (CIR) Expert Panel stated that this ingredient was safe as used in cosmetic products. The Expert Panel reviewed newly available studies since that assessment, along with updated information regarding types and concentrations of use. The Panel confirmed the safety of Arachidyl Propionate in the practices of use and concentrations as given in Table 3, and did not reopen the safety assessment.

TABLE 3
Current and historical cosmetic product uses and concentrations for Arachidyl Propionate

Product category	1981 ingredient uses (Elder 1990)	2005 ingredient uses (FDA 2006)	1981 concentrations (Elder 1990) (%)	2006 concentrations (CTFA 2006) (%)
Eye makeup				
Eyebrow pencils	—	—	—	5
Fragrance products				
Other	1	1	≤ 5	—
Noncoloring hair care products				—
Other	—	4	—	—
Makeup				
Foundations	—	2	—	2
Lipsticks	24	8	≤ 5–10	0.5–7
Makeup bases	—	2	—	—
Other		1	—	—
Nail care products				
Nail polishes and enamels	—	—	—	0.04
Other	—	—	—	0.04
Personal hygiene products				
Other	—	—	—	0.001
Shaving products				
Aftershave lotions	—	—	—	0.002
Skin care products				
Skin cleansing creams, lotions, liquids, and pads	—	—	—	0.002
Face and neck creams, lotions, powder, and sprays	3[a]	3	≤ 5[a]	2
Body and hand creams, lotions, powder, and sprays		12		0.002–3
Moisturizers	3	3	≤ 5	2
Night creams, lotions, powder, and sprays	—	4	—	—
Other	—	7	—	—
Total uses/ranges for Arachidyl Propionate	31	47	3–10	0.001–7

[a]These categories were combined when the original safety assessment was performed and are now two separate categories.

DISCUSSION

Arachidyl Propionate was used in 31 cosmetic products in 1981, based on voluntary reports provided to FDA by industry, with concentrations of use ranging from 3% to 10% (Elder 1990). In 2005, Arachidyl Propionate was reportedly used in 47 cosmetic products (FDA 2006). Data from an industry survey in 2006 indicated that Arachidyl Propionate was used at concentrations ranging from 0.001% to 7% (CTFA 2006).

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Benzalkonium Chloride

CONCLUSION

In a safety assessment of Benzalkonium Chloride (Elder 1989), the Cosmetic Ingredient Review (CIR) Expert Panel stated that Benzalkonium Chloride, at concentrations up to 0.1% free, active ingredient, is safe as a cosmetic ingredient as presently used. The Expert Panel reviewed newly available studies since that assessment, along with updated information regarding types and concentration of use, noting that these studies were similar to those already included in the original safety assessment and, therefore, raised no new safety issues. The Panel confirmed the safety of Benzalkonium Chloride at concentrations up to 0.1% free, active ingredient and did not reopen the safety assessment.

DISCUSSION

Benzalkonium Chloride was used in 83 products in 1986, based on voluntary reports provided to FDA by industry, at concentrations of ≤0.1% to 5% (Elder 1989). Data provided to FDA in 2006 indicated that Benzalkonium Chloride was used in 89 products (FDA 2006). Current use concentration data from a cosmetics industry survey indicated that Benzalkonium Chloride is being used in cosmetics at concentrations ranging from 0.01% to 0.5% (CTFA 2006). The available usage and use concentration data are given in Table 4 as a function of product category.

It appears that the maximum reported use concentration of 0.5% (i.e., 0.5% Benzalkonium Chloride in a liquid towelette [personal hygiene product]) exceeds the Panel's 0.1% concentration limit for Benzalkonium Chloride, which is based on skin irritation and sensitization potential. However, it was determined that this is not a concern because Benzalkonium Chloride is bound in the liquid towelette product, and, therefore, the concentration that comes in contact with the skin would be expected to be <0.1%.

The Panel recognizes that there are data gaps regarding use and concentration of this ingredient. However, the overall information available on the types of products in which this ingredient is used and at what concentration indicate a pattern of use, which was considered by the Expert Panel in assessing safety.

The Panel noted that Benzalkonium Chloride can increase the dermal penetration of other chemicals (e.g., betamethasone phosphate). The CIR Expert Panel advised formulators to consider this if the other ingredients in a formulation include those found safe by CIR on the basis that they did not penetrate the skin.

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TABLE 4
Historical and current cosmetic product uses and concentrations for Benzalkonium Chloride

Product category	1986 uses (Elder 1989)	2006 uses (FDA 2006)	1986 concentrations (Elder 1989) (%)	2006 concentrations (CTFA 2006) (%)
Baby products	4[a]		≤ 0.1 – 1[a]	
Shampoos		—		0.03
Lotions, oils, powders, and creams		2		0.03–0.1
Other		2		0.03
Bath products				
Soaps and detergents	—	—	—	0.1
Eye makeup	6[a]		≤ 0.1 – 1[a]	
Eyebrow pencils		—		0.02
Eyeliners		—		0.02
Eye shadow		—		0.02
Eye lotion		1		0.02
Eye makeup remover		10		0.01–0.05
Mascaras		—		0.02–0.1
Other		—		0.02
Fragrance Products				
Colognes and toilet waters	—	1	—	0.1
Perfumes	—	—	—	0.1
Powders	—	—	—	0.08–0.1
Sachets	—	—	—	0.1
Other	—	—	—	0.1
Noncoloring hair products	45[a]		≤ 0.1 – 5[a]	
Conditioners		12		0.05
Straighteners		—		0.1
Permanent waves		—		0.1
Rinses		2		0.1
Shampoos		—		0.1
Tonics, dressings, etc.		7		0.02–0.05
Hair-coloring products				
Dyes and colors	—	—	—	0.02
Tints	—	—	—	0.02
Rinses	—	—	—	0.02
Color sprays	—	—	—	0.02
Lighteners with color	—	—	—	0.02
Bleaches	—	1	—	0.02
Makeup				
Blushers	—	—	—	0.1
Face powders	—	—	—	0.1
Foundations	—	—	—	0.1
Makeup bases	—	—	—	0.1
Makeup fixatives	—	—	—	0.1
Other	—	—	—	0.1
Nail care products				
Cuticle softeners	—	—	—	0.1
Creams and lotions	—	1	—	—
Other	—	1	-	0.01–0.1

(Continued on next page)

TABLE 4
Historical and current cosmetic product uses and concentrations for Benzalkonium Chloride *(Continued)*

Product category	1986 uses (Elder 1989)	2006 uses (FDA 2006)	1986 concentrations (Elder 1989) (%)	2006 concentrations (CTFA 2006) (%)
Oral hygiene products				
Mouthwashes and breath fresheners	—	—	—	0.03
Personal hygiene products	11[a]		≤ 0.1 – 1[a]	
Underarm deodorants		1		0.1
Douches		—		0.1
Feminine deodorants		—		0.1
Other		1		0.1—0.5[b]
Shaving products				
Aftershave lotions	—	—	—	0.1
Shaving cream	—	—	—	0.1
Shaving soap	—	—	—	0.1
Skin care products				
Skin cleansing creams, lotions, liquids, and pads	6	17	≤ 0.1 – 1	0.05–0.1
Depilatories	—	—	—	0.1
Face and neck creams, lotions, powder, and sprays	—	3	—	0.06–0.1
Body and hand creams, lotions, powder, and sprays	—	3	—	0.09–0.1
Foot powders and sprays	—	1	—	0.08–0.1
Moisturizers	4	1	≤ 0.1 – 1	0.1
Night creams, lotions, powders, and sprays	—	1	≤ 0.1 – 1	0.1
Paste masks/mud packs	—	3	—	0.1
Skin fresheners	—	5	—	0.1
Other	7	2	≤ 0.1 – 1	0.1
Suntan products				
Suntan gels, creams, and liquids	—	1	—	—
Total uses/ranges for Benzalkonium Chloride	83	89	≤ 0.1 – 5	0.01–0.5

[a]These categories were combined when the original safety assessment was performed and are now two or more separate categories.
[b]0.5% in a towelette product.

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Cetearyl Alcohol, Cetyl Alcohol, Isostearyl Alcohol, Myristyl Alcohol, and Behenyl Alcohol

CONCLUSION

In a safety assessment of Cetearyl Alcohol, Cetyl Alcohol, Isostearyl Alcohol, Myristyl Alcohol, and Behenyl Alcohol (Elder, 1988), the Cosmetic Ingredient review (CIR) Expert Panel stated these cosmetic ingredients were safe in the present practices of use. The Expert Panel reviewed newly available studies since that assessment, along with updated information regarding types and concentrations of use. The Panel confirmed the safety of Cetearyl Alcohol, Cetyl Alcohol, Isostearyl Alcohol, Myristyl Alcohol, and Behenyl Alcohol in the practices of use and concentrations as given in Table 5, and did not reopen the safety assessment.

DISCUSSION

Cetearyl Alcohol was used in 56 cosmetic products in 1982, based on voluntary reports provided to FDA by industry, with use concentrations ranging from >1% to 25% (Elder 1988). In 2006, Cetearyl Alcohol was reportedly used in 1435 cosmetic products (FDA 2006). Data from an industry survey in 2005 indicated

TABLE 5
Current and historical cosmetic product uses and concentrations for Cetearyl Alcohol, Cetyl Alcohol, Isostearyl Alcohol, Myristyl Alcohol, and Behenyl Alcohol

Product category	1982 ingredient uses (Elder 1988)	2006 ingredient uses (FDA 2006)	1982 concentrations (Elder 1988) (%)	2005 concentrations (CTFA 2005) (%)
		Cetearyl Alcohol		
Baby products				
Shampoos	—	—	—	1
Lotions, oils, powders, and creams	—	2	—	<0.3–5
Other	—	1	—	1
Bath products				
Oils, tablets, and salts	—	—	—	0.001–0.1
Soaps and detergents	1	3	>10–25	0.004–2
Bubble baths	—	—	—	0.001
Other	—	5	—	4
Eye makeup				
Eyebrow pencils	—	1	—	—
Eyeliners	—	1	—	0.4–7
Eye shadow	—	1	—	0.4
Eye lotions	—	2	—	1–5
Eye makeup remover	1	1	>1–5	2–3
Mascara	1	2	>1–5	0.8–3
Other	—	2	—	0.9
Fragrance products				
Colognes and toilet waters	—	—	—	0.0002–1
Perfumes	—	9	—	—
Other	—	8	—	5
Noncoloring hair care products				
Conditioners	6	152	>0.1–10	0.05–9
Sprays/aerosol fixatives	—	—	—	0.6–2
Straighteners	3	16	>5–10	5–7
Permanent waves	—	11	—	—
Rinses	1	9	>0.1–1	8
Shampoos	1	9	>1–5	0.2–14
Tonics, dressings, etc.	—	8	—	4–10
Wave sets	—	5	—	4
Other	—	28	—	0.7–6
Hair-coloring products				
Dyes and colors	—	579	—	2–15
Tints	—	26	—	—
Rinses	—	—	—	3
Color sprays	—	2	—	—
Lighteners with color	—	10	—	1
Bleaches	—	9	—	2–9
Other	—	43	—	2[a]
Makeup				
Blushers	—	—	—	2–5
Face powders	—	1	—	—
Foundations	2	10	>0.1–1	1–6
Lipsticks	—	13	—	2–6

(Continued on next page)

TABLE 5
Current and historical cosmetic product uses and concentrations for Cetearyl Alcohol, Cetyl Alcohol, Isostearyl Alcohol, Myristyl Alcohol, and Behenyl Alcohol *(Continued)*

Product category	1982 ingredient uses (Elder 1988)	2006 ingredient uses (FDA 2006)	1982 concentrations (Elder 1988) (%)	2005 concentrations (CTFA 2005) (%)
Makeup bases	—	1	—	3
Rouges	1	—	>0.1–1	—
Other	1	3	>1–5	0.5–6
Nail care products				
Cuticle softeners	—	1	—	—
Nail polishes and enamels	—	—	—	0.8–8
Other	—	1	—	—
Personal hygiene products				
Underarm deodorants	—	1	—	0.3–6
Other	1	6	>5–10	0.4–4
Shaving products				
Aftershave lotions	2	2	>0.1–1	0.001–2
Shaving cream	4	2	>1–5	0.001–10
Other	—	—	—	0.8
Skin care products				
Skin cleansing creams, lotions, liquids, and pads	4	53	>1–5	0.5–5
Depilatories	—	15	—	3–8
Face and neck creams, lotions, powder, and sprays	11[b]	46	>0.1–10[b]	1–6
Body and hand creams, lotions, powder, and sprays		105		1–13
Foot powders and sprays	—	4	—	6
Foot creams	—	—	—	1–9
Moisturizers	7	122	>0.1–25	0.6–10
Night creams, lotions, powder, and sprays	2	16	>1–5	0.4–5
Paste masks/mud packs	4	18	>1–10	0.5–4
Skin fresheners	—	1	—	—
Other	3	39	>1–25	2–5
Suntan products				
Suntan gels, creams, liquids, and sprays	—	7	—	0.3–3
Indoor tanning preparations	—	17	—	2–6
Other	—	6	—	<0.03–2
Total uses/ranges for Cetearyl Alcohol	56	1435	>0.1–25	0.0002–15
	Cetyl Alcohol			
Baby products				
Shampoos	—	—	—	2
Lotions, oils, powders, and creams	12	16	>0.1–5	2–3
Other	—	1	—	—
Bath products				
Oils, tablets, and salts	8	—	≤0.1–5	2
Soaps and detergents	1	11	>5–10	0.0005–7
Bubble baths	—	—	—	0.2
Other	4	4	>0.1–5	3–4
Eye makeup				
Eyebrow pencils	6	14	>1–5	3–7
Eyeliners	30	16	≤ 0.1–5	0.2–5
Eye shadow	169	19	≤ 0.1–10	0.2–3

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TABLE 5
Current and historical cosmetic product uses and concentrations for Cetearyl Alcohol, Cetyl Alcohol, Isostearyl Alcohol, Myristyl Alcohol, and Behenyl Alcohol *(Continued)*

Product category	1982 ingredient uses (Elder 1988)	2006 ingredient uses (FDA 2006)	1982 concentrations (Elder 1988) (%)	2005 concentrations (CTFA 2005) (%)
Eye lotions	1	7	>0.1–1	0.8–3
Eye makeup remover	4	8	>0.1–5	0.5–2
Mascara	8	34	>0.1–5	1–5
Other	26	20	>0.1–5	0.2–3
Fragrance products				
Colognes and toilet waters	12	3	>0.1–25	0.04–2
Perfumes	7	—	>1–50	0.1–9
Powders	4	—	>0.1–5	0.4
Sachets	59	16	>0.1–50	—
Other	26	28	≤0.1–10	0.4–3
Noncoloring hair care products				
Conditioners	163	332	≤0.1–25	2–8
Sprays/aerosol fixatives	2	—	≤0.1–5	—
Straighteners	32	—	>0.1–25	1–7
Permanent waves	3	4	≤0.1–1	0.6
Rinses	52	20	≤0.1–5	1–7
Shampoos	9	59	≤0.1–5	0.08–4
Tonics, dressings, etc.	17	27	≤0.1–10	0.000002–8
Wave sets	—	—	—	6
Other	9	28	≤0.1–5	—
Hair-coloring products				
Dyes and colors	1	198	>0.1–1	3–10
Tints	—	1	—	—
Rinses	—	—	—	4
Shampoos	2	1	>0.1–1	—
Color sprays	—	1	—	—
Lighteners with color	—	7	—	—
Bleaches	12	29	>0.1–10	0.7–5
Other	5	7	>0.1–25	—
Makeup				
Blushers	40	10	≤0.1–25	0.01–3
Face powders	24	14	>0.1–5	0.4–3
Foundations	68	58	≤0.1–10	0.2–7
Leg and body paints	3	—	>0.1–1	—
Lipsticks	573	215	≤0.1–25	0.9–7
Makeup bases	134	66	≤0.1–10	3
Rouges	13	—	≤0.1–5	0.000005
Makeup fixatives	2	3	≤0.1–1	1
Other	11	37	>0.1–5	1–7
Nail care products				
Cuticle softeners	6	8	>0.1–5	1–5
Creams and lotions	8	2	>0.1–10	1–2
Nail polishes and enamels	—	—	—	0.03
Nail polish and enamel removers	—	—	—	0.0001
Other	2		>0.1–5	0.03–4[c]

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TABLE 5
Current and historical cosmetic product uses and concentrations for Cetearyl Alcohol, Cetyl Alcohol, Isostearyl Alcohol, Myristyl Alcohol, and Behenyl Alcohol *(Continued)*

Product category	1982 ingredient uses (Elder 1988)	2006 ingredient uses (FDA 2006)	1982 concentrations (Elder 1988) (%)	2005 concentrations (CTFA 2005) (%)
Personal hygiene products				
Underarm deodorants	20	27	>0.1–5	0.00008–8
Feminine deodorants	1	—	>0.1–1	—
Other	29	10	>0.1–10	0.2–2
Aftershave lotions	11	14	≤0.1–5	0.01–2
Preshave lotions	1	1	>0.1–1	0.01
Shaving cream	25	25	≤0.1–5	0.2–2
Other	10	8	>0.1–5	<0.3
Skin care products				
Skin cleansing creams, lotions, liquids, and pads	169	207	≤0.1–25	0.2–15
Depilatories	9	10	>1–10	0.8
Face and neck creams, lotions, powder, and sprays	322[b]	138	≤0.1–25[b]	0.1–7
Body and hand creams, lotions, powder, and sprays		341		.04–5
Foot powders and sprays	2	9	>0.1–5	2–5
Foot cream	—	—	—	6
Moisturizers	287	381	≤0.1–10	0.4–3
Night creams, lotions, powder, and sprays	95	96	≤0.1–10	1–4
Paste masks/mud packs	13	51	>0.1–5	0.8–5
Skin fresheners	2	3	>0.1–5	0.5–5
Skin lighteners	13	N/A[d]	>0.1–5	N/A[d]
Hormone preparations	3	N/A[d]	>0.1–10	N/A[d]
Wrinkle smoothers (removers)	6	—	>0.1–5	—
Other	47	152	>0.1–25	0.8–3
Suntan products				
Suntan gels, creams, liquids and sprays	42	44	≤0.1–5	0.6–4
Indoor tanning preparations	7	26	>0.1–5	0.3–2
Other	12	18	>0.1–5	0.3
Total uses/ranges for Cetyl Alcohol	2694	2931	≤0.1–50	0.000002–15
	Isostearyl Alcohol			
Baby products				
Other	—	—	—	3[f]
Bath products				
Oils, tablets, and salts	2	—	>1–5	—
Soaps and detergents	—	—	—	3
Eye makeup				
Eyeliners	—	—	—	44
Eye shadow	—	1	—	0.001–45
Eye makeup remover	—	—	—	1
Mascara	—	2	—	—
Fragrance products				
Colognes and toilet waters	3	1	>1–50	—
Perfumes	—	1	—	35
Other	2	—	>1–10	—

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TABLE 5
Current and historical cosmetic product uses and concentrations for Cetearyl Alcohol, Cetyl Alcohol, Isostearyl Alcohol, Myristyl Alcohol, and Behenyl Alcohol *(Continued)*

Product category	1982 ingredient uses (Elder 1988)	2006 ingredient uses (FDA 2006)	1982 concentrations (Elder 1988) (%)	2005 concentrations (CTFA 2005) (%)
Noncoloring hair care products				
Conditioners	1	7	>0.1–1	0.06–2
Rinses	2	—	>0.1–5	—
Tonics, dressings, etc.	—	1	—	5
Other	—	3	—	—
Hair-coloring products				
Dyes and colors	—	—	—	0.2
Makeup				
Blushers	21	—	>1–5	—
Face powders	—	—	—	0.001–0.02
Foundations	—	—	—	0.05–3
Lipsticks	5	1	>0.1–25	0.001–50
Makeup bases	—	—	—	14
Rouges	—	—	—	0.1
Other	1	1	>25–50	0.01–45[g]
Nail care products				
Nail polishes and enamels	—	—	—	0.03
Personal hygiene products				
Underarm deodorants	—	—	—	0.02–3
Shaving products				
Aftershave lotions	—	—	—	0.05–2
Skin care products				
Face and neck creams, lotions, powder, and sprays	1[b]	—	>0.1–1[b]	0.02–2
Body and hand creams, lotions, powder, and sprays		2		0.05–5
Foot powders and sprays	—	—	—	0.05
Moisturizers	2	—	>0.1–5	—
Night creams, lotions, powder, and sprays	1	—	>1–5	—
Other	—	—	—	0.03
Suntan products				
Suntan gels, creams, liquids and sprays	—	—	—	0.2–0.8
Total uses/ranges for Isostearyl Alcohol	41	20	>0.1–50	0.001–50
	Myristyl Alcohol			
Bath products				
Soaps and detergents	—	2	—	0.003–0.4
Eye makeup				
Eyebrow pencils	—	—	—	2
Eyeliners	—	—	—	2
Eye shadow	—	—	—	0.5–5
Fragrance products				
Colognes and toilet waters	—	—	—	0.0005–12
Noncoloring hair care products				
Conditioners	1	10	>1–5	0.000001–7
Sprays/aerosol fixatives	—	—	—	0.0001
Straighteners	—	—	—	0.6
Shampoos	1	1	>0.1–1	0.00007–1

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TABLE 5
Current and historical cosmetic product uses and concentrations for Cetearyl Alcohol, Cetyl Alcohol, Isostearyl Alcohol, Myristyl Alcohol, and Behenyl Alcohol *(Continued)*

Product category	1982 ingredient uses (Elder 1988)	2006 ingredient uses (FDA 2006)	1982 concentrations (Elder 1988) (%)	2005 concentrations (CTFA 2005) (%)
Tonics, dressings, etc.	—	—	—	0.05–5
Other	—	7	—	—
Hair coloring products				
Dyes and colors	—	36	—	—
Makeup				
Face powders	—	—	—	0.0001
Foundations	1	1	>1–5	—
Lipsticks	—	—	—	0.9–4
Makeup bases	4	—	>1–5	—
Other	—	—	—	2
Nail care products				
Cuticle softeners	1	—	>1–5	—
Personal hygiene products				
Underarm deodorants	—	1	—	0.0001–3
Shaving products				
Aftershave lotions	1	3	>0.1–1	3
Beard softeners	2	—	>1–5	—
Shaving cream	1	—	>1–5	2–3
Other	2	4	>0.1–5	<0.3
Skin care products				
Skin cleansing creams, lotions, liquids, and pads	1	4	≤ 0.1	—
Face and neck creams, lotions, powder, and sprays	5[b]	6	>0.1–5[b]	0.0001–6
Body and hand creams, lotions, powder, and sprays		4		0.07–6
Moisturizers	8	10	>0.1–5	0.5
Night creams, lotions, powder, and sprays	1	—	>0.1–1	3
Paste masks/mud packs	1	—	>0.1–1	—
Skin fresheners	—	—	—	0.8–2
Other	1	2	>1–5	0.07
Suntan products				
Suntan gels, creams, liquids, and sprays	—	—	—	1–2
Indoor tanning preparations	—	—	—	1
Total uses/ranges for Myristyl Alcohol	31	91	≤0.1–5	0.000001–12
	Behenyl Alcohol			
Baby products				
Lotions, oils, powders, and creams	—	—	—	0.9
Other	—	—	—	3[e]
Bath products				
Soaps and detergents	—	—	—	0.2–3
Eye makeup				
Eyebrow pencils	4	6	>10–25	26
Eyeliners	18	22	>5–50	0.5–17
Eye shadow	9	1	>10–50	4–25
Eye lotions	—	2	—	0.6
Mascara	—	—		0.4–1

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TABLE 5
Current and historical cosmetic product uses and concentrations for Cetearyl Alcohol, Cetyl Alcohol, Isostearyl Alcohol, Myristyl Alcohol, and Behenyl Alcohol *(Continued)*

Product category	1982 ingredient uses (Elder 1988)	2006 ingredient uses (FDA 2006)	1982 concentrations (Elder 1988) (%)	2005 concentrations (CTFA 2005) (%)
Other	—	—	—	0.4–2
Fragrance products				
Other	—	1	—	1
Noncoloring hair care products				
Conditioners	—	27	—	0.3–10
Permanent waves	—	—	—	1
Rinses	—	1	—	2
Shampoos	—	11	—	1–2
Tonics, dressings, etc.	—	1	—	—
Other	—	2	—	—
Hair coloring products				
Bleaches	—	—	—	3
Makeup				
Foundations	—	—	—	0.4–2
Lipsticks	11	4	>10–50	0.01–0.5
Makeup bases	—	15	—	3
Makeup fixatives	—	1	—	0.4
Other	1	6	>10–25	1–2
Nail care products				
Cuticle softeners	—	1	—	—
Personal hygiene products		—	—	—
Underarm deodorants	—	—	—	0.06–0.3
Shaving products				
Aftershave lotions	—	1	—	—
Preshave lotions	—	—	—	1
Other	—	—	—	<0.3
Skin care products				
Skin cleansing creams, lotions, liquids, and pads	—	6	—	0.2–2
Face and neck creams, lotions, powder, and sprays	—[b]	22	—[b]	0.7–8
Body and hand creams, lotions, powder, and sprays		9		0.6–4
Foot powders and sprays	—	1	—	4
Moisturizers	—	66	—	0.2–3
Night creams, lotions, powder and sprays	—	9	—	0.8–4
Paste masks/mud packs	—	5	—	0.5–4
Skin fresheners	—	2	—	1
Other	—	7	—	0.3–4
Suntan products				
Suntan gels, creams, liquids and sprays	—	—	—	0.4–3
Indoor tanning preparations	—	1	—	0.9–3
Total uses/ranges for Behenyl Alcohol	43	230	>5—50	0.01–26

[a] Temporary, wash-off hair color.
[b] In 1982, these categories were combined.
[c] Includes a nail conditioner at 3%.
[d] No longer considered a cosmetic product category.
[e] Soap at 3%.
[f] Concealer at 45%.

that Cetearyl Alcohol was used at concentrations ranging from 0.0002% to 15% (CTFA 2005).

The most widely used ingredient of this group, Cetyl Alcohol, was used in 2694 cosmetic products in 1982, based on voluntary reports provided to FDA by industry, with use concentrations ranging from ≤0.1% to 50% (Elder 1988). In 2006, Cetyl Alcohol was reportedly used in 2931 cosmetic products (FDA 2006). Data from an industry survey in 2005 indicated that Cetearyl Alcohol was used at concentrations ranging from 0.000002% to 15% (CTFA 2005).

Isostearyl Alcohol was used in 41 cosmetic products in 1982, based on voluntary reports provided to FDA by industry, with use concentrations ranging from >1% to 50% (Elder 1988). In 2006, Isostearyl Alcohol was reportedly used in 20 cosmetic products (FDA 2006). Data from an industry survey in 2005 indicated that Isostearyl Alcohol was used at concentrations ranging from 0.001% to 50% (CTFA 2005).

Myristyl Alcohol was used in 31 cosmetic products in 1982, based on voluntary reports provided to FDA by industry, with use concentrations ranging from ≤0.1% to 5% (Elder 1988). In 2006, Myristyl Alcohol was reportedly used in 91 cosmetic products (FDA 2006). Data from an industry survey in 2005 indicated that Cetearyl Alcohol was used at concentrations ranging from 0.000001% to 12% (CTFA 2005).

Behenyl Alcohol was used in 43 cosmetic products in 1982, based on voluntary reports provided to FDA by industry, with use concentrations ranging from >5% to 50% (Elder 1988). In 2006, Behenyl Alcohol was reportedly used in 230 cosmetic products (FDA 2006). Data from an industry survey in 2005 indicated that Behenyl Alcohol was used at concentrations ranging from 0.01% to 26% (CTFA 2005).

The CIR Expert Panel recognized that certain ingredients in this group are reportedly used in a given product category, but the concentration of use is not available. For other ingredients in this group, information regarding use concentration for specific product categories is provided, but the number of such products is not known. In still other cases, an ingredient is not in current use, but may be used in the future. Although there are gaps in knowledge about product use, the overall information available on the types of products in which these ingredients are used and at what concentration indicate a pattern of use.

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Cocoamphoacetate, Cocoamphopropionate, Cocoamphodiacetate, and Cocoamphodipropionate

CONCLUSION

In a safety assessment of Cocoamphoacetate, Cocoamphopropionate, Cocoamphodiacetate, and Cocoamphodipropionate (Elder, 1990), the Cosmetic Ingredient review (CIR) Expert Panel stated these cosmetic ingredients were safe as used. The Expert Panel reviewed newly available studies since that assessment, along with updated information regarding types and concentrations of use. The Panel confirmed the safety of Cocoamphoacetate, Cocoamphopropionate, Cocoamphodiacetate, and Cocoampho-dipropionate in the practices of use and concentrations as given in Table 6, and did not reopen the safety assessment.

DISCUSSION

The Panel noted that the names for these ingredients in the *International Cosmetic Ingredient Dictionary and Handbook* (Gottschalck and McEwen 2006) have changed—they are now Sodium Cocoamphoacetate, Sodium Cocoamphopropionate, Disodium Cocoamphodiacetate, and Disodium Cocoamphodipropionate, respectively.

Sodium Cocoamphoacetate was used in five cosmetic products in 1989, based on voluntary reports provided to FDA by industry with concentrations ranging from >1% to 10% (Elder 1990). In 2005, Sodium Cocoamphoacetate was reportedly used in 46 cosmetic products (FDA 2006). Data from an industry survey in 2006 indicated that Sodium Cocoamphoacetate was used at concentrations ranging from 0.9% to 18% (CTFA 2006).

Sodium Cocoamphopropionate was not in use in 1989, based on voluntary reports provided to FDA by industry (Elder 1990). In 2005, Sodium Cocoamphopropionate was reportedly used in seven cosmetic products (FDA 2006). Data from an industry survey in 2006 indicated that Sodium Cocoamphopropionate was used at concentrations ranging from 0.3% to 10% (CTFA 2006).

Disodium Cocoamphodiacetate was used in 30 cosmetic products in 1989, based on voluntary reports provided to FDA by industry with concentrations ranging from ≤0.1% to 50% (Elder 1990). In 2005, Disodium Cocoamphodiacetate was reportedly used in 194 cosmetic products (FDA 2006). Data from an industry survey in 2006 indicated that Sodium Cocoamphodiacetate was used at concentrations ranging from 0.0006% to 12% (CTFA 2006).

Disodium Cocoamphodipropionate was used in 17 cosmetic products in 1989, based on voluntary reports provided to FDA by industry with concentrations ranging from >1% to 25% (Elder 1990). In 2005, Disodium Cocoampho-dipropionate was reportedly used in 72 cosmetic products (FDA 2006). Data from an industry survey in 2006 indicated that Sodium Cocoamphodipropionate was used at concentrations ranging from 0.008% to 15% (CTFA 2006).

The CIR Expert Panel recognized that certain ingredients in this group are reportedly used in a given product category, but the concentration of use is not available. For other ingredients in this group, information regarding use concentration for specific product categories is provided, but the number of such products is not known. Although there are gaps in knowledge about product use, the overall information available on the types of products in which these ingredients are used and at what concentration indicate a pattern of use. The Panel acknowledged that uses of these ingredients in leave-on products has increased, including uses in baby products, but considered that the original safety assessment adequately addressed the safety of leave-on uses.

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Diazolidinyl Urea

CONCLUSION

In a safety assessment of Diazolidinyl Urea (Elder 1990), the Cosmetic Ingredient Review (CIR) Expert Panel stated that this ingredient is safe up to a maximum concentration of 0.5%. The Expert Panel reviewed newly available studies since that assessment, along with updated information regarding types and concentration of use. The Panel confirmed that Diazolidinyl Urea is safe up to a maximum concentration of 0.5%, which is consistent with the present practices of use and concentrations given in Table 7, and did not reopen the safety assessment.

DISCUSSION

Diazolidinyl Urea was used in 95 products in 1987, based on voluntary reports provided to FDA by industry, at concentrations

TABLE 6
Historical and current cosmetic product uses and concentrations for Sodium Cocoamphoacetate, Sodium Cocoamphopropionate, Disodium Cocoamphodiacetate, and Disodium Cocoamphodipropionate

Product category	1989 uses (Elder 1990)	2005 uses (FDA 2006)	1989 concentrations (Elder 1990) (%)	2006 concentrations (CTFA 2006) (%)
		Sodium Cocoamphoacetate		
Baby Care				
Other baby care	—	—	—	4[b]
Bath				
Soaps and detergents	—	4	—	3–18
Bubble baths	—	4	—	0.09
Noncoloring hair care				
Conditioners	—	3	—	2
Permanent waves	—	1	—	—
Shampoos	5	11	>1–10	1–6
Tonics, dressings, etc.	—	—	—	0.1
Hair coloring				
Dyes and colors	—	—	—	0.7
Other hair coloring	—	2	—	—
Makeup				
Othermakeup	—	—	—	3
Personal hygiene				
Douches	—	—	—	0.8–2
Other personal hygiene	—	18	—	—
Skin care products				
Skin cleansing creams, lotions, liquids, and pads	—	3	—	2–5
Total uses/ranges for Sodium Cocoamphoacetate	5	46	>1–10	0.09–18
		Sodium Cocomaphopropionate		
Bath				
Other bath	—	—	—	10[c]
Noncoloring hair care products				
Conditioners	—	—	—	3–5
Permanent waves	—	—	—	0.3
Shampoos	—	3	—	8
Tonics, dressings, etc.	—	2	—	—
Other	—	2	—	—
Total uses/ranges for Sodium Cocoamphopropionate	—	7	—	0.3–10
		Disodium Cocoamphodiacetate		
Baby Care				
Shampoos	—	1	—	2–7
Other	—	7	—	—
Bath				
Oils, tablets, and salts	—	1	—	—
Soaps and detergents	—	7	—	2–9
Capsules	—	1	—	—
Other bath	—	6	—	4–8
Eye makeup				
Eye makeup remover	—	15	—	0.005–0.8
Mascara	—		—	0.05

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TABLE 6
Historical and current cosmetic product uses and concentrations for Sodium Cocoamphoacetate, Sodium Cocoamphopropionate, Disodium Cocoamphodiacetate, and Disodium Cocoamphodipropionate *(Continued)*

Product category	1989 uses (Elder 1990)	2005 uses (FDA 2006)	1989 concentrations (Elder 1990) (%)	2006 concentrations (CTFA 2006) (%)
Noncoloring hair care				
Straighteners	—	1	—	—
Permanent waves	—	8	—	—
Shampoos	13	82	>1–50	2–8
Hair coloring				
Dyes and colors	—	1	—	—
Rinses	—	—	—	5
Shampoos	—	4	—	—
Makeup				
Foundations	—	—	—	0.0006
Lipsticks	—	—	—	5
Personal hygiene				
Feminine deodorants	—	—	—	0.09
Other personal hygiene	—	5	—	0.05–2[d]
Shaving products				
Aftershave lotions	—	1	—	—
Shaving cream	—	1	—	—
Skin care				
Cleansing creams, lotions, etc.	10	36	≤0.1–25	0.5–12
Depilatories	—	—	—	5
Face and neck skin care	—	3	—	0.03
Foot powders and sprays	—	—	—	0.2
Moisturizers	—	2	—	—
Night skin care	—	—	—	0.06
Paste masks/mud packs	—	7	—	—
Skin fresheners	—	2	—	—
Other skin care	—	2	—	0.04—10
Suntan				
Suntan gels, creams, liquids and sprays	—	—	—	0.004
Other suntan	—	1	—	—
Miscellaneous other cosmetics[a]	7[a]	—	≤0.1–10[a]	—
Total uses/ranges for Disodium Cocoamphodiacetate	30	194	≤0.1–50	0.0006–12
Disodium Cocoamphodipropionate				
Baby care				
Other baby care	—	1	—	—
Bath				
Soaps and detergents	—	3	—	8
Noncoloring hair care products				
Conditioners	—	14	—	0.2
Sprays/aerosol fixatives	—	—	—	1
Shampoos	8	27	>1–25	15
Tonics, dressings, etc.	-	4	—	0.8
Other bath	7	15	>1–25	—

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TABLE 6
Historical and current cosmetic product uses and concentrations for Sodium Cocoamphoacetate, Sodium Cocoamphopropionate, Disodium Cocoamphodiacetate, and Disodium Cocoamphodipropionate *(Continued)*

Product category	1989 uses (Elder 1990)	2005 uses (FDA 2006)	1989 concentrations (Elder 1990) (%)	2006 concentrations (CTFA 2006) (%)
Hair coloring				
Dyes and colors	—	3	—	0.008
Personal hygiene				
Other personal hygiene	—	—	—	0.5[e]
Skin care				
Cleansing creams, lotions, etc.	2	5	>1–10	7
Total uses/ranges for Disodium Cocoamphodipropionate	17	72	>1–25	0.008–15

[a]Category previously used which does not correspond to any current categories.
[b]Baby cleansing gel.
[c]Shower gel.
[d]Perineal wipe (0.05%); feminine wash (2%).
[e]Perineal wipe.

of ≤1% to 5% (Elder 1990). Data provided to FDA in 2006 indicated that Diazolidinyl Urea was being used in 756 products (FDA 2006). Current use concentration data from a cosmetics industry survey indicated that Diazolidinyl Urea was being used in cosmetics at concentrations ranging from 0.00003% to 0.5% (CTFA 2006). Ingredient use and concentration data are included in Table 7.

The Expert Panel recognized data gaps regarding use and concentration of this ingredient. However, the overall information available on types of products in which this ingredient is used and at what concentration indicate a pattern of use, which was considered by the Expert Panel in assessing safety.

Diazolidinyl Urea is a formaldehyde-releasing preservative, and the presence of free formaldehyde in cosmetic products preserved with this ingredient was addressed in the original discussion by noting that, due to the skin sensitivity of some individuals to formaldehyde, this ingredient should be used at the minimum effective concentration (not to exceed 0.2%) and that there was no indication that the use of Diazolidinyl Urea as used in cosmetic products would release formaldehyde at concentrations that would exceed the limits recommended for formaldehyde (Elder 1990).

In a presentation at the December 4–5, 2006, CIR Expert Panel meeting, Dr. John Merianos, with International Specialty Products, reviewed the chemistry of formaldehyde releasing preservatives. He emphasized the fundamental equilibrium that exists between these compounds and free formaldehyde itself, resulting in a steady state of availability of formaldehyde in aqueous solutions. Knowing the chemistry, he suggested, allows a calculation of the amount of free formaldehyde, which exists in a low balance. For example, at a use level of 0.6% Imidazolidinyl Urea (aq.), the steady state concentration of free formaldehyde is only 0.23 ppm, and for Diazolidinyl Urea at 0.5% (aq.), the level of free formaldhyde is only 0.40 ppm. Dr. Merianos concluded that not all formaldehyde releasing preservatives are equivalent, but, in all cases, the level of free formaldehyde is sufficiently low that maximum use levels of the preservatives cannot result in hazardous levels of formaldehyde.

The Expert Panel recognized that while earlier studies (Elder 1990) indicated that Diazolidinyl Urea was not genotoxic in bacterial or mammalian systems, but acknowledged that more recent genotoxicity data (Pfuhler and Wolf 2002) in which the authors concluded that this preservative is a weak mutagen. The Panel's review of the experimental procedure determined that the assay included a preincubation step that allowed the generation of additional free formaldehyde; this was likely the reason for the weak mutagenic effect.

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TABLE 7
Historical and current cosmetic product uses and concentrations for Diazolidinyl Urea

Product category (FDA 2005)	1987 ingredient uses (Elder 1990)	2006 ingredient uses (FDA 2006)	1987 concentrations (Elder 1990) (%)	2006 concentrations (CTFA 2006) (%)
Baby products	3[a]		≤ 1[a]	
Shampoos		1		0.2–0.3
Lotions, oils, powders, and creams		2		0.2–0.3
Other		1		0.2
Bath products				
Oils, tablets, and salts	—	3	—	0.3
Soaps and detergents	—	10	—	0.0005–0.3
Bubble baths	10	3	≤ 10	0.0002
Other		21	—	0.3
Eye makeup	11[a]		≤ 1[a]	
Eyebrow pencils		—		0.2
Eyeliners		11		0.2–0.4
Eye shadow		30		0.1–0.5
Eye lotions		2		0.2–0.3
Eye makeup remover		4		0.002–0.3
Mascara		31		0.09–0.3
Other		18		0.2–0.3[b]
Fragrance products				
Colognes and toilet waters	—	—	—	0.0009–0.2
Perfumes	—	—	—	0.0003–0.3
Powders	8	9	≤ 1 – 5	0.2–0.3
Other	—	2	—	0.0006
Noncoloring hair products	3[a]		≤ 1[a]	
Conditioners		39		0.2–0.3
Sprays/aerosol fixatives		1		0.3
Straighteners		4		—
Rinses		6		0.2–0.3
Shampoos		36		0.2–0.5
Tonics, dressings, etc.		44		0.06–0.4
Wave sets		2		0.3
Other		28		0.3
Hair-coloring products				
Dyes and colors	—	8	—	0.1
Rinses	—	—	—	0.2–0.3
Color sprays	—	1	—	—
Makeup	16[a]		≤ 1[a]	
Blushers		13		0.3–0.5
Face Powders		19		0.2–0.3
Foundations		14		0.2–0.5
Lipstick		—		0.05–0.5
Makeup bases		14		0.2–0.3
Rouges		—		0.3
Makeup fixatives		2		—
Other		6		0.2–0.3[c]
Nail care products	3[a]		≤ 1[a]	
Basecoats and undercoats		1		—

(Continued on next page)

TABLE 7
Historical and current cosmetic product uses and concentrations for Diazolidinyl Urea *(Continued)*

Product category (FDA 2005)	1987 ingredient uses (Elder 1990)	2006 ingredient uses (FDA 2006)	1987 concentrations (Elder 1990) (%)	2006 concentrations (CTFA 2006) (%)
Cuticle softeners		1		0.2–0.3
Nail creams and lotions		—		0.2–0.3
Other		1		0.05[d]
Personal hygiene products				
Underarm deodorants	—	2	—	—
Douches	—	—	—	0.2
Feminine deodorants	—	—	—	0.2
Other	—	15	—	0.2–0.3
Shaving products				
Aftershave lotions	1	7	≤ 1	0.2–0.4
Preshave lotions	—	—	—	0.2–0.3
Shaving cream	—	6	—	0.05–0.3
Other	—	3	—	0.08–0.3
Skin care products				
Skin cleansing creams, lotions, liquids, and pads	7	44	≤ 1	0.0006–0.3
Face and neck creams, lotions, powder, and sprays	—	32	—	0.001–0.4
Body and hand creams, lotions, powder, and sprays	—	53	—	0.0002–0.4
Foot powders and sprays	—	1	—	0.00003–0.3[e]
Moisturizers	26	98	≤ 1	0.2–0.4
Night creams, lotions, powder, and sprays	—	11	—	0.2–0.3
Paste masks/mud packs	—	29	—	0.2–0.3
Skin fresheners	—	22	—	0.2–0.3
Other	7	37	≤ 1	0.002–0.5[f]
Suntan products				
Suntan gels, creams, liquids, and sprays	—	3	—	0.2–0.4
Indoor tanning preparations	—	5	—	0.2–0.3
Other	—	—	—	0.2
Total uses/ranges for Diazolidinyl Urea	95	756	**≤1–5**	0.00003–0.5

[a]These categories were combined when the original safety assessment was performed and are now two or more separate categories.
[b]0.2% reported in an eye cream.
[c]0.2% reported in a concealer.
[d]Manicure exfoliator.
[e]0.3% reported in a foot cream.
[f]0.002% reported in a hand sanitizer; 0.2% in a pore strip and a toner; and 0.3% in a facial refinisher and a massage oil.

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Disperse Black 9

CONCLUSION

In a safety assessment of disperse black 9 (Elder 1986), the Cosmetic Ingredient Review (CIR) Expert Panel stated that this ingredient was safe as a cosmetic ingredient in cosmetics in present practices of use and concentration. No new safety test data were found since that assessment, but the Expert Panel did review current use and concentration data. The panel confirmed the safety of Disperse Black 9 in the practices of use and concentrations given in Table 8.

DISCUSSION

The CIR Expert Panel concluded that the available epidemiology studies are insufficient to conclude there is a causal relationship between hair dye use and cancer and other end points; see Hair Dye Epidemiology for a discussion and list of references. A presentation of the available hair dye epidemiology data is available at http://www.cir-safety.org/findings.shtml. The Panel stated that use of direct hair dyes, such as Disperse Black 9, although not the focus in all investigations, appears to have little

TABLE 8
Current and historical cosmetic product uses and concentrations for Disperse Black 9

Product category	1981 ingredient uses (Elder 1988)	2002 ingredient uses (FDA 2002)	1981 concentrations (Elder 1988) (%)	2005 concentrations (CTFA 2005) (%)
Hair dyes and colors	69	101	< 0.1–1	0.3–0.5
Total uses/ranges for Disperse Black 9	69	101	≤ 0.1–1	0.3–0.5

evidence of an association with adverse events as reported in epidemiology studies.

The Expert Panel recognized that Disperse Black 9 may be a sensitizer. However, hair dyes containing these ingredients, as coal tar hair dye products are exempt from the principal adulteration provision and from the color additive provisions in sections 601 and 706 of the Federal Food, Drug, and Cosmetic Act, when the label bears a caution statement and patch test instructions for determining whether the product causes skin irritation. The Expert Panel expects that continuing to follow this procedure will identify prospective individuals who would have an irritation/sensitization reaction and allow them to avoid significant exposures.

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DMDM Hydantoin

CONCLUSION

In a safety assessment on the formaldehyde releasing preservative, DMDM Hydantoin (Elder 1987), the Cosmetic Ingredient Review (CIR) Expert Panel concluded that this ingredient was safe as used in cosmetic products. Studies available since that safety assessment was completed, along with updated information regarding uses and use concentrations, were considered. The Expert Panel confirmed that DMDM Hydantoin is safe in the practices of use and concentration given in Table 9, and determined not to reopen this safety assessment.

DISCUSSION

DMDM Hydantoin was reported as being used in a total of 115 cosmetic products in 1981. Data provided by FDA in 2002 indicated that DMDM Hydantoin was being used in 963 cosmetic products. Current use concentration data indicate a slightly lower maximum use concentration of 0.8%, compared to the 1% maximum use concentration that was reported in 1981.

The Panel noted that the present practices of use of DMDM Hydantoin would not result in more than 0.2% free formaldehyde, which is the concentration limit for free formaldehyde in cosmetic products that was previously established by the CIR Expert Panel. The Panel also noted that the North American Contact Dermatitis Group (NACDG) patch test results for DMDM Hydantoin in large populations of patients with suspected allergic contact dermatitis indicated that the frequency of allergic reactions to DMDM Hydantoin has not increased over time.

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TABLE 9
Current and historical cosmetic product uses and concentrations for DMDM Hydantoin

Product category	1981 ingredient uses (Elder 1987)	2002 ingredient uses (FDA 2002)	1981 concentrations (Elder 1987) (%)	2005 concentrations (CTFA 2005) (%)
Baby products				
Shampoos	—	4	—	0.2
Lotions, oils, powders, and creams	—	1	—	0.2[a]
Other	—	3	—	0.3–0.5
Bath products				
Oils, tablets, and salts	—	3	—	0.0003–0.3
Soaps and detergents	6	68	>0.1–1	0.1–0.8
Bubble baths	5	14	≤0.1–1	0.2–0.3
Other	1	—	—	0.1–0.5[b]
Eye makeup				
Eye shadow	—	1	—	0.02
Eye lotion	1	—	>0.1–1	0.00001
Eye makeup remover	—	—	—	0.0003–0.3
Mascara	—	4	—	0.004–0.4
Other	—	7	—	0.002–0.1
Fragrance products				
Colognes and toilet waters	—	1	—	0.2
Other	—	10	—	0.1
Noncoloring hair products				
Conditioners	19	189	≤0.1–1	0.1–0.4
Sprays/aerosol fixatives	—	3	—	—
Permanent waves	—	5	—	—
Rinses	7	1	>0.1–1	—
Shampoos	35	234	≤0.1–1	0.0005–0.6
Tonics, dressings, etc.	4	95	>0.1–1	0.2–0.5
Wave sets	—	11	—	—
Other	—	65	—	0.2–0.3[c]
Hair coloring products				
Dyes and colors	—	10	—	—
Shampoos	1	10	>0.1–1	—
Other	—	1	—	—
Foundations	8	8	>0.1–1	0.004–0.1
Makeup				
Lipsticks	—	3	—	0.1–0.2
Makeup bases	5	5	>0.1–1	—
Other	—	1	—	0.004–0.25
Nail care products				
Nail polishes and enamels	—	1	—	0.006
Personal hygiene products				
Underarm deodorants	—	—	—	0.2
Other	1	27	>0.1–1	0.06–0.5[d]
Shaving products				
Aftershave lotions	—	—	—	0.2–0.7
Shaving cream	—	1	—	0.09–0.2
Other	—	7	—	0.2

(Continued on next page)

TABLE 9
Current and historical cosmetic product uses and concentrations for DMDM Hydantoin *(Continued)*

Product category	1981 ingredient uses (Elder 1987)	2002 ingredient uses (FDA 2002)	1981 concentrations (Elder 1987) (%)	2005 concentrations (CTFA 2005) (%)
Skin care products				
Skin cleansing creams, lotions, liquids, and pads	3	40	>0.1–1	0.2–0.5
Face and neck creams, lotions, powder, and sprays	9[e]	13	>0.1–1[e]	0.0002–0.3
Body and hand creams, lotions, powder, and sprays		40		0.0004–0.5[f]
Foot powders and sprays	—	1	—	0.2
Moisturizers	6	44	≤0.1–1	0.01–0.3
Night creams, lotions, powders, and sprays	2	5	>0.1–1	0.0005–0.3
Paste masks	—	8	—	0.2–0.3
Skin fresheners	—	8	—	—
Other	2	—	—	0.0001–0.3
Suntan Products				
Suntan gels, creams, liquids, and sprays	—	3	—	0.08
Indoor tanning preparations	—	7	—	0.001–0.4
Other	—	1	—	—
Total uses/ranges for DMDM Hydantoin	115	963	≤0.1–1	0.00001–0.8

[a]Reported for a baby wipe product.
[b]0.3% and 0.5% reported for body wash products.
[c]0.2% reported for a hair gel.
[d]0.2% reported for a vulvar area cleanser and 0.5% for a hand wash product.
[e]These categories were combined in 1981 and are now two separate categories.
[f]0.3% reported for body and hand sprays.

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Ethyl Acetate and Butyl Acetate

CONCLUSION

In a safety assessment of Ethyl Acetate and Butyl Acetate (Elder 1989), the Cosmetic Ingredient Review (CIR) Expert Panel stated that both are safe as cosmetic ingredients in the present practices of use and concentration. The Expert Panel

TABLE 10
Historical and current cosmetic product uses and concentrations for Ethyl Acetate and Butyl Acetate

Product category	1987 uses (Elder 1989)	2006 uses (FDA 2006)	1987 concentrations (Elder 1989) (%)	2006 concentrations (CTFA 2006) (%)
	Ethyl Acetate			
Bath products				
Soaps and detergents	—	—	—	0.01
Other	—	1		—
Eye makeup				
Eye shadow	—	—	—	0.001
Noncoloring hair products				
Conditioners	—	—	—	0.002–0.003
Sprays/aerosol fixatives	—		—	0.002
Shampoos	—	2	—	0.002–0.009
Tonics, dressings, etc.	—	—	—	0.002
Nail care products				
Basecoats and undercoats	12	42	>10–50	37–68
Cuticle softeners	—	—	—	68
Creams and lotions	—	2	—	49–68
Extenders	505[a]	—	>1–50[a]	68
Nail polishes and enamels		375		21–68
Nail polish and enamel removers	17	22	>10–>50	2–85
Other	25	34	>1–50	20–68
Oral hygiene products				
Dentifrices	—	—	—	0.0006–0.005
Personal hygiene products				
Underarm deodorants	—	—	—	0.1
Skin care products				
Body and hand creams, lotions, powder and sprays	—	—	—	0.0003
Paste masks/mud packs	—	—	—	0.000002
Other	—	—		
Total uses/ranges for Ethyl Acetate	559	478	>1–>50	0.000002–85
	Butyl Acetate			
Nail care products				
Basecoats and undercoats	31	42	>10–50	30–72
Cuticle softeners	—	—	—	72
Creams and lotions	—	2	—	36–72
Extenders	505[a]	—	>1–50[a]	72
Nail polishes and enamels		362		25–72
Nail polish and enamel removers	3	5	≤0.1–50	50–72
Other	25	34	>1–50	25–72
Skin care products				
Skin cleansing creams, lotions, liquids, and pads	2	—	>10–>50	—
Total uses/ranges for Butyl Acetate	566	445	≤0.1–50	25–72

[a]These categories were combined when the original safety assessment was performed and are now two separate categories.

reviewed newly available studies since that assessment, along with updated information regarding types and concentration of use. The Panel confirms that Ethyl and Butyl Acetate are safe in the practices of use and concentrations given in Table 10 and did not reopen the safety assessment.

DISCUSSION

Ethyl Acetate and Butyl Acetate were used in 559 and 566 products, respectively, in 1987, based on voluntary reports provided to FDA by industry, at concentrations of >1% to >50% (Ethyl Acetate) and ≤0.1% to 50% (Butyl Acetate) (Elder 1989).

Data provided to FDA in 2006 indicated that Ethyl Acetate and Butyl Acetate are being used in 478 and 445 products, respectively (FDA 2006). Current use concentration data from a cosmetics industry survey indicated that Ethyl Acetate is being used in cosmetics at concentrations ranging from 0.000002% to 85% and that Butyl Acetate is being used at concentrations ranging from 25% to 72% (CTFA 2006).

The Panel noted that Ethyl Acetate is now being used at low concentrations (≤0.01%) in a variety of products, such as, eye make-up, hair, and oral hygiene products. It is believed that these new uses are actually fragrance uses of Ethyl Acetate, because this ingredient is used to enhance the rose fragrance for floral scents. The Panel determined that because the new uses are associated with low use concentrations of Ethyl Acetate, the available data support their safety in cosmetic products.

The Panel recognizes that there are data gaps regarding use and concentration of this ingredient. However, the overall information available on the types of products in which this ingredient is used and at what concentration indicate a pattern of use, which was considered by the Expert Panel in assessing safety.

The Panel noted that Ethyl Acetate and Butyl Acetate can increase the dermal penetration of other chemicals (e.g., estradiol and cortisone). The CIR Expert Panel advised formulators to consider this if the other ingredients in a formulation include those found safe by CIR on the basis that they did not penetrate the skin.

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Methylene Chloride

CONCLUSION

In a safety assessment on Methylene Chloride (Elder 1988), the CIR Expert Panel concluded that this ingredient is safe for use in cosmetic products designed for brief discontinuous use. Studies available since this safety assessment was completed, along with updated information regarding use in cosmetic products, were considered by the CIR Expert Panel. After reviewing the available data, but most importantly, noting that the FDA has promulgated a regulation prohibiting the use of Methylene Chloride in cosmetic products, the Panel determined not to reopen this safety assessment.

DISCUSSION

Frequency of use data submitted to FDA in 1986 indicated that Methylene Chloride was not being used in cosmetic products; however, similar data submitted to FDA in 2005 indicated that it was being used in three hair sprays. According to the Cosmetic Toiletry and Fragrance Association (CTFA 2005), the three hair sprays are no longer being made and Methylene Chloride is not currently listed as a cosmetic ingredient in the *International Cosmetic Ingredient Dictionary and Handbook.*

She CIR Expert Panel acknowledged that the FDA has promulgated a regulation prohibiting the use of Methylene Chloride in cosmetic products and that the earlier safety assessment on Methylene Chloride (Elder 1988) is superceded by FDA's regulatory action.

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2-Methyl-5-Hydroxyethylaminophenol

CONCLUSION

In a safety assessment of 2-Methyl-5-Hydroxyethylaminophenol (Elder 1990), the Cosmetic Ingredient Review (CIR) Expert Panel stated that this ingredient was safe as used in cosmetic products. The Expert Panel reviewed newly available studies since that assessment, along with updated information regarding types and concentrations of use. The Panel confirmed that 2-Methyl-5-Hydroxyethylaminophenol is safe in the practices of use and concentration, as given in Table 11, and did not reopen the safety assessment.

DISCUSSION

2-Methyl-5-Hydroxyethylaminophenol is an ingredient in oxidative hair dyes used in 54 hair-coloring preparations in 1981, based on voluntary reports provided to FDA by industry, with concentrations of use ranging from ≤0.1% to 5% (Elder 1990). In 2005, 2-Methyl-5-Hydroxyethylaminophenol was reportedly used in 133 cosmetic products (FDA 2006). Data from an industry survey in 2006 indicated that 2-Methyl-5-Hydroxyethylaminophenol was used at concentrations ranging from 0.5% to 1% (CTFA 2006).

The CIR Expert Panel has concluded that the available epidemiology studies are insufficient to conclude there is a causal relationship between hair dye use and cancer and other end points; see Hair Dye Epidemiology for a discussion and list of references. A presentation of the available hair dye epidemiology data is available at http://www.cir-safety.org/findings.shtml.

Whereas this ingredient is an oxidative hair color, one use in a color spray was reported by industry to FDA. Although it is unlikely that an oxidative hair color would be used in a color spray, previous considerations of hair spray technology have demonstrated that the particle sizes produced are not respirable.

The Expert Panel recognizes that 2-Methyl-5-Hydroxy ethylaminophenol is used as a hair dye ingredient and may be a sensitizer. However, hair dyes containing this ingredient, as coal tar hair products, are exempt from the principle adulteration provision and from the color additive provisions in sections 601

TABLE 11
Current and historical uses and concentrations of 2-Methyl-5-Hydroxyethylaminophenol in cosmetics

Product category	1981 ingredient uses (Elder 1990)	2005 ingredient uses (FDA 2006)	1981 concentrations (Elder 1990) (%)	2006 concentrations (CTFA 2006) (%)
Hair-coloring preparations				
Hair dyes and colors	54	132	≤0.1–5	0.5–1
Color sprays	—	1	—	—
Total uses/ranges for 2-Methyl-5-Hydroxyethylaminophenol	54	133	≤ 0.1–5	0.5–1

and 706 of the Federal Food, Drug, and Cosmetic Act, when the label bears a caution statement and patch test instructions for determining whether the product causes skin irritation. The Expert Panel expects that following this procedure will identify prospective individuals who have had an irritation/sensitization reaction and allow them to avoid significant exposure.

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TABLE 12
Historical and current cosmetic product uses and concentrations for Resorcinol and 2-Methylresorcinol

Product category (FDA 2005)	1981 uses (Elder 1986)	2006 uses (FDA 2006)	1981 concentrations (Elder 1986) (%)	2006 concentrations (CTFA 2006) (%)
	2-Methylresorcinol			
Hair-coloring products				
Dyes and colors	104	555	≤0.1–1	0.6–2
Tints	—	8	—	—
Lighteners with color	—	1	—	—
Nail care products				
Basecoats and undercoats	—	1	—	—
Total uses/ranges for 2-Methylresorcinol	104	565	≤0.1–1	0.6–2
	Resorcinol			
Bath products				
Soaps and detergents	1	—	>0.1–1	—
Noncoloring hair products				
Shampoos	1	1	>0.1–1	—
Hair coloring products				
Dyes and colors	464	1193	≤0.1–5	0.5–5
Tints	7	16		2
Rinses	—	—	—	2
Color sprays	—	1	—	2
Lighteners with color	—	3	—	2
Bleaches	—	—	—	2
Other	—	—	—	2
Makeup				
Blushers	—	—	—	0.1
Face powders	—	—	—	0.1
Foundations	—	—	—	0.1
Makeup bases	1	—	>1–5	0.1
Makeup fixatives	—	—	—	0.1
Other	—	—	—	0.1
Nail care products				
Basecoats and undercoats	—	1	—	—
Shaving products				
Aftershave lotions	—	1	—	—
Skin care products				
Skin cleansing creams, lotions, liquids, and pads	4	2	≤0.1–1	0.1
Depilatories	—	—	—	0.1
Face and neck creams, lotions, powder and sprays	—	1	—	0.1–1
Body and hand creams, lotions, powder and sprays	—	1	—	0.1
Foot powders and sprays	—	—	—	0.1
Moisturizers	—	—	—	0.1
Night	—	—	—	0.1
Paste masks (mud packs)	—	1	—	0.1
Skin fresheners	1	—	>0.1–1	0.1
Other	3	1	> 0.1–5	0.1
Total uses/ranges for Resorcinol	482	1222	≤0.1–5	0.5–5

Resorcinol and 2-Methylresorcinol

CONCLUSION

In a safety assessment of Resorcinol and 2-Methylresorcinol (Elder 1986), the Cosmetic Ingredient Review (CIR) Expert Panel stated that both are safe as cosmetic ingredients in the present practices of use and concentration. The Expert Panel reviewed newly available studies since that assessment, along with updated information regarding types and concentration of use. The Panel confirmed that Resorcinol and 2-Methylresorcinol are safe in the practices of use and concentrations given in Table 12 and did not reopen the safety assessment.

DISCUSSION

Resorcinol and 2-Methylresorcinol are dye intermediates in permanent, oxidative hair dyes used in 482 and 104 products, respectively, in 1981, based on voluntary reports provided to FDA by industry, at concentrations of ≤0.1% to 5% and ≤0.1% to 1%, respectively (Elder 1986). Data provided to FDA in 2006 indicated that Resorcinol and 2-Methylresorcinol are being used in 1222 and 565 products, respectively (FDA 2006). Current use concentration data from a cosmetics industry survey indicated that Resorcinol is being used in cosmetics at concentrations ranging from 0.5% to 5% and that 2-Methylresorcinol is being used at concentrations ranging from 0.6% to 2% (CTFA 2006).

The Expert Panel recognized that there are data gaps regarding use and concentration of these ingredients. However, the overall information available on types of products in which these ingredients are used and at what concentrations indicate a pattern of use, which was considered by the Expert Panel in assessing safety.

The Expert Panel also considered that these ingredients may be sensitizers. However, as coal tar derivatives, products containing these ingredients are exempt from the principle adulteration provision and from the color additive provision in sections 601 and 706 of the Federal Food, Drug, and Cosmetic Act, when the label bears a caution statement and patch test instructions for determining whether the product causes skin irritation. The Panel expects that following this procedure will identify prospective individuals who have had an irritation/sensitization reaction and allow them to avoid significant exposure.

The CIR Expert Panel has concluded that the available epidemiology studies are insufficient to conclude there is a causal relationship between hair dye use and cancer and other end points; see Hair Dye Epidemiology for a discussion and list of references. A presentation of the available hair dye epidemiology data is available at http://www.cir-safety.org/findings.shtml.

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Petroleum Distillates

CONCLUSION

In a safety assessment of Petroleum Distillates (Elder 1986), the Cosmetic Ingredient Review (CIR) Expert Panel stated that this ingredient was safe as a cosmetic ingredient at the current concentrations of use. The Expert Panel reviewed updated information regarding types and concentration of use. The Panel confirmed that Petroleum Distillates are safe in the practices of use and concentrations given in Table 13 and did not reopen the safety assessment.

TABLE 13
Historical and current cosmetic product uses and concentrations for Petroleum Distillates

Product category	1981 uses (Elder 1986)	2005 uses (FDA 2006)	1981 concentrations (Elder 1986) (%)	2006 concentrations (CTFA 2006) (%)
Eye makeup				
Eyeliners	1	2	>50	19
Eye shadow	78	3	>1–>50	3–32
Eye makeup remover	1	1	>25–50	61
Mascara	18	18	>10–>50	12–64
Other	3	2	>5–>50	5–55
Noncoloring hair care products				
Other	—	—	—	4–82
Hair coloring products				
Dyes and colors	1	—	>25–50	—
Other	3	—	—	—
Makeup				
Blushers	—	—	—	2
Foundations	—	2	—	—
Lipsticks	—	—	—	3
Makeup bases	4	—	>5–10	—
Other	1	—	>10–25	—
Nail care products				
Nail polishes and enamels	1	—	>10–25	—
Other	—	—	—	40[a]
Skin care products				
Skin cleansing creams, lotions, liquids, and pads	1	—	>50	5–37
Depilatories	1	—	>25–50	—
Other	—	1	—	—
Total uses/ranges for Petroleum Distillates	113	29	>1–>50	2–82

[a]40% in a drying enhancer.

DISCUSSION

The Expert Panel noted that there has been a name change in the *International Cosmetic Ingredient Dictionary and Handbook* from the singular to the plural, Petroleum Distillates, and that cosmetic grade Petroleum Distillates consist of C_{10} to C_{16} paraffinic, naphthenic, and isoparaffinic hydrocarbons with a boiling point range of 350°C to 500°C. There has also been a correction of the CAS number to 8002-05-9.

Petroleum Distillates were used in 113 products in 1981, based on voluntary reports provided to FDA by industry with concentrations of use ranging from <1% to >50% (Elder 1986). In 2006, Petroleum Distillates was reportedly used in 29 products (FDA 2006). Data from an industry survey in 2006 indicated that Petroleum Distillates were used at concentrations ranging from 2% to 82% (CTFA 2006).

New unpublished data submitted by industry included three Draize eye irritation tests on eye area products that contained Petroleum Distillates at 34.4% to 39.7%. The products were found to be nonirritating. A mascara with 61.57% Petroleum Distillates was found to be non-irritating in an opthalmological safety evaluation. Repeat-insult patch tests performed with mascara with Petroleum Distillates at 61.57% resulted in a non-irritating and non-sensitizing result. Petroleum Distillates are nonirritating and nonsensitizing to the eye area.

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TABLE 14
Historical and current cosmetic product uses and concentrations for Phenethyl Alcohol

Product category	1987 uses (Elder 1990)	2005 uses (FDA 2006)	1987 concentrations (Elder 1990) (%)	2005 concentrations (CTFA 2006) (%)
Eye makeup	25[a]	—	≤ 1[a]	—
Eyebrow pencils		—		.02
Eyeliners		1		—
Eye makeup remover		2		0.1
Mascara		9		0.2–0.8
Fragrance products	2[a]	—	≤ 1[a]	—
Noncoloring hair care products				
Shampoos	3	—	≤ 1	—
Makeup	2[a]	—	≤ 1[a]	—
Blushers		—		0.008
Face powders		1		—
Foundations		1		0.03
Other		4		0.005
Skin care products	12[b]	—	≤ 1[b]	—
Skin cleansing creams, lotions, liquids, and pads		1		0.01
Depilatories	1	—	≤ 1	—
Face and neck creams, lotions, powder and sprays		—		0.003
Body and hand creams, lotions, powder, and sprays		3		—
Moisturizers		1		—
Night creams, lotions, powder, and sprays		1		—
Other		3		—
Suntan products				
Suntan gels, creams, liquids, and sprays	—	1	—	0.01
Total uses/ranges for Phenethyl Alcohol	45	28	≤1	0.003–0.8

[a]Uses in broad product categories only were reported in 1987, whereas current uses are reported in specific product categories.
[b]Except for depilatories, uses were reported only for the broad category of skin care products in 1987.

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Phenethyl Alcohol

CONCLUSION

In a safety assessment of Phenethyl Alcohol (Elder 1990), the Cosmetic Ingredient Review (CIR) Expert Panel stated that this ingredient was safe up to 1% in cosmetic products. The Expert Panel reviewed newly available studies since that assessment, along with updated information regarding types and concentrations of use. The Panel confirmed Phenethyl Alcohol is safe at a concentration up to 1%, and did not reopen the safety assessment.

DISCUSSION

Phenethyl Alcohol was used in 45 cosmetic products in 1987, based on voluntary reports provided to FDA by industry, with concentrations of use at less than 1% (Elder 1990). In 2005, Phenethyl Alcohol was reportedly used in 28 cosmetic products (FDA 2006). Data from an industry survey in 2006 indicated that Arachidyl Propionate was used at concentrations ranging from 0.003% to 0.8% (CTFA 2006). Table 14 presents the available use and concentration information. The Panel stated that if industry had an interest in increasing the 1% limit, it would be necessary to reopen the safety assessment and for industry to provide the relevant data.

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Polyquaternium-10

CONCLUSION

In a safety assessement of Polyquaternium-10 (Elder 1988), the CIR Expert Panel stated that this ingredient is safe as a cosmetic ingredient in the present practices of use. The Expert Panel reviewed newly available studies since that assessment, along with updated information regarding types and concentrations of use. The Panel confirmed that Polyquaternium-10 is safe in the practices of use and concentrations given in Table 15 and did not reopen the safety assessment.

DISCUSSION

Polyquaternium-10 was used in 139 cosmetic products in 1981, based on voluntary reports provided to FDA by industry, with concentrations of use between $\leq$0.1% and 5 % (Elder 1990). In 2005, Polyquaternium-10 reportedly was used in 396 cosmetic products (FDA 2006). Data from an industry survey in 2005 indicated that Arachidyl Propionate was used at concentrations ranging from 0.004% to 1.5% (CTFA 2005).

The Expert Panel did note that Polyquaternium-10 is used in several product categories, including baby products, in which this ingredient had not been reportedly used. Because Polyquaternium 10 absorbs in the hair, but not skin, the Expert Panel considered that these new product categories did not raise any issues of safety.

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Retinol and Retinyl Palmitate

CONCLUSION

In a safety assessment on Retinol and Retinyl Palmitate (Elder, 1987), the CIR Expert Panel stated that these ingredients are safe as a cosmetic ingredients in the present practices of use and concentration. Studies available since that safety assessment was completed, along with updated information regarding uses and use concentrations, were considered by the CIR Expert Panel. The Panel confirmed that Retinol and Retinyl Palmitate are safe in the practices of use and concentrations given in Table 16 and did not reopen the safety assessment.

DISCUSSION

The number of ingredient uses reported for Retinol and Retinyl Palmitate in 1981 were 138 and 102, respectively; and use concentrations were $\leq$0.1% to 5% for both (Elder 1987). Data provided by FDA in 2002 indicated 50 and 677 uses for Retinol and Retinyl Palmitate, respectively. Current use concentration data for Retinol are between 0.00006% and 2%, and for Retinyl Palmitate, between 0.000001% and 1.7%.

It was noted that both Retinol and Retinyl Palmitate are used in hair sprays, and that inhalation toxicity data on these ingredients are/were not available. The Expert Panel reasoned that the two ingredients can be used safely in aerosolized products if particulates from those products are not respirable. Because the particle size of anhydrous hair sprays (60 - 80 μm) and pump hair sprays (>80 μm) is large compared to the median aerodynamic diameter of 4.25 $\pm$ 1.5 μm for a respirable particulate

TABLE 15
Historical and current cosmetic product uses and concentrations for Polyquaternium-10

Product category	1981 uses (Elder 1988)	2002 uses (FDA 2002)	1981 concentrations (Elder 1988) (%)	2005 concentrations (CTFA 2005) (%)
Baby products				
Shampoos	—	4	—	0.02–0.4
Other	—	1	—	0.1
Bath products				
Oils, tablets, and salts	—	2	—	0.2–0.5
Soaps and detergents	1	32	>0.1–1	0.1–0.5
Bubble baths	1	1	>0.1–1	—
Other	—	1	—	0.1–1[a]
Eye makeup				
Eyebrow pencils	—	—	—	0.1
Eye lotions	—	1	—	—
Eye makeup remover	—	1	—	—
Mascara	5	7	≤ 0.1	0.3
Other	—	—	—	1
Fragrance products				
Other	—	3	—	—
Noncoloring hair care products				
Conditioners	16	37	≤0.1–5	0.2–0.5
Sprays/aerosol fixatives	1	1	>0.1–1	—
Permanent waves	6	5	>0.1–5	0.1
Rinses	—	2	—	—
Shampoos	62	167	≤0.1–5	0.1–1
Tonics, dressings, etc.	4	20	≤0.1–1	0.05–0.5
Wave sets	6	6	≤0.1–5	—
Other	1	14	>0.1–1	1.5
Hair-coloring products				
Dyes and colors	—	3	—	—
Tints	—	35	—	—
Shampoos	3	8	>0.1–1	—
Other	—	2	—	0.2[b]
Makeup				
Foundations	—	—	—	0.02–0.05
Leg and body paints	—	—	—	0.2
Makeup bases	2	—	≤ 0.1	—
Personal hygiene products				
Other	—	9	—	0.1–0.3[c]
Shaving products				
Aftershave lotions	—	—	—	0.004
Shaving cream	—	—	—	0.1
Other	—	3	—	—
Skin care products				
Skin cleansing creams, lotions, liquids, and pads	6	17	≤0.1–1	0.1–0.9
Depilatories	—	1	—	—
Face and neck creams, lotions, powder, and sprays	8[d]	—	≤0.1–1[d]	0.05–0.5
Body and hand creams, lotions, powder, and sprays		3		—

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TABLE 15
Historical and current cosmetic product uses and concentrations for Polyquaternium-10 *(Continued)*

Product category	1981 uses (Elder 1988)	2002 uses (FDA 2002)	1981 concentrations (Elder 1988) (%)	2005 concentrations (CTFA 2005) (%)
Foot powders and sprays	—	—	—	0.1
Moisturizers	12	1	≤0.1–1	0.8
Night creams, lotions, powder, and sprays	1	2	≤0.1	0.2
Paste masks/mud packs	1	2	≤ 0.1	—
Skin fresheners	1	1	≤ 0.1	—
Wrinkle smoothers (removers)	1	—	≤0.1–1	—
Other	1	3	>0.1–1	0.07–0.3
Suntan products				
Suntan gels, creams, liquids, and sprays	—	—	—	0.1
Indoor tanning preparations	—	1	—	—
Total uses/ranges for Polyquaternium-10	139	396	≤0.1–5	0.004–1.5

[a] A body wash product.
[b] A coloring shampoo product.
[c] 0.1% reported in a handwash product.
[d] In 1981, these categories were combined and have since been separated.

mass, it was considered unlikely that inhalation would be a route of exposure of lung tissue.

The Panel also noted that Retinol and Retinyl Palmitate absorb light in the low UVA range and that neither photoirritation nor photoallergy data were included in the final safety assessment. However, recent photoirritation and photoallergy data on sunscreen products containing Retinol at concentrations ranging from 0.04% to 0.09% or 0.01% Retinyl Palmitate were provided by the cosmetics industry and these data demonstrated no advesrse reactions. These concentrations are consistent with the current use concentration data that were provided. After considering these data and the the lack of clinical reports of Retinol- or Retinyl Palmitate–induced photoirritation/photoallergy in the published literature, it was agreed that no concerns relating to the phototoxicity/photoallergenicity potential of Retinol or Retinyl Palmitate in cosmetic products are warranted.

The Panel is aware of an ongoing NTP photococarcinogenicity study on Retinyl Palmitate, and is interested in reviewing the results of this study as soon as they are available. Relative to this ongoing research, the Panel noted that data from the published literature indicate that the epoxy photodecomposition products of Retinyl Palmitate are phototoxic, but not photomutagenic.

After reviewing in vitro percutaneous absorption data (human skin) on Retinyl Palmitate that were published after the final safety assessment was issued, the Panel noted that the results of this study demonstrated a very low rate of absorption when acetone (not a cosmetic vehicle) served as the vehicle. It was agreed that no issues relating to the percutaneous absorption of Retinyl Palmitate are apparent.

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TABLE 16
Historical and current cosmetic product uses and concentrations for Retinol and Retinyl Palmitate

Product category	1981uses (Elder 1987)	2002 uses (FDA 2002)	1981 concentrations (Elder 1987) (%)	2005 concentrations (CTFA 2005) (%)
	Retinol			
Baby products				
Lotions, oils, powders, and creams	1	—	>0.1–1	—
Bath products				
Oils, tablets and salts	—	4	—	0.03
Bubble baths	—	1	—	0.005
Other	—	—	—	0.0003[a]
Eye makeup				
Eye shadow	—	1	—	—
Eye lotion	—	—	—	0.003–0.1
Eye makeup remover	1	—	≤0.1	
Other	—	2	—	—
Noncoloring hair products				
Conditioners	2	—	—	—
Sprays/aerosol fixatives	1	—	≤ 0.1	<0.01
Rinses	1	—	—	—
Shampoos	4	—	≤ 0.1	—
Tonics, dressings, etc.	2	1	≤0.1–1	0.01
Wave sets	4	—	≤ 0.1	—
Other	1	—	>0.1–1	—
Makeup				
Blushers	1	1	—	—
Face powders	1	—	—	—
Foundations	4	1	≤ 0.1	0.0005–0.2
Lipsticks	5	2	—	0.1–0.2
Makeup bases	5	1	≤ 0.1	—
Nail care products				
Creams and lotions	1	—	—	0.001
Other	1	1	≤ 0.1	—
Personal hygiene products				
Other	1	—	—	0.01
Shaving products				
Aftershave lotions	1	—	—	—
Preshave lotions	1	—	—	—
Skin care products				
Skin cleansing creams, lotions, liquids, and pads	7	1	≤0.1–1	0.00006–0.2
Face and neck creams, lotions, powder, and sprays	20[b]	2	≤0.1–5[b]	0.01–0.3
Body and hand creams, lotions, powder, and sprays		6		0.00006–0.09
Moisturizers	39	7	≤0.1–1	0.01–0.3
Night creams, lotions, powders, and sprays	11	3	≤0.1–1	0.003–0.1
Paste masks	4	—	≤ 0.1	0.02
Skin fresheners	4	1	≤ 0.1	—
Hormone preparations	3	N/A[c]	≤0.1–1	N/A[c]
Wrinkle smoothers (removers)	1	N/A[c]	≤ 0.1	N/A[c]
Other	8	15	≤0.1–1	0.06–1.6[d]
Total uses/ranges for Retinol	138	50	≤0.1–5	0.00006–2

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TABLE 16
Historical and current cosmetic product uses and concentrations for Retinol and Retinyl Palmitate

Product category	1981uses (Elder 1987)	2002 uses (FDA 2002)	1981 concentrations (Elder 1987) (%)	2005 concentrations (CTFA 2005) (%)
		Retinyl Palmitate		
Baby products				
Lotions, oils, powders, and creams	—	1	—	—
Bath products				
Soaps and detergents	—	16	—	0.001–0.01
Bath products				
Oils, tablets and salts	—	—	—	0.00001–0.06
Bubble baths	1	1	≤ 0.1	0.06
Other	1	5	≤ 0.1	0.001–0.01[e]
Eye makeup				
Eyebrow pencils	—	1	—	0.1–0.5
Eyeliner	—	—	—	0.05–0.1
Eye shadow	—	7	—	0.1
Eye lotions	—	8	—	0.001–0.6
Eye makeup remover	—	2	—	0.001–0.06
Mascara	—	5	—	0.000001–0.05
Other	4	15	≤0.1–1	0.06–0.1
Fragrance products				
Colognes and toilet waters	—	1	—	0.001–0.02
Perfumes	—	1	—	—
Powders	—	7	—	0.01–0.05
Other	—	4	—	0.001–0.02
Noncoloring hair products				
Conditioners	2	25	≤ 0.1	0.0001–1
Sprays/aerosol fixatives	—	4	—	0.005–0.009
Rinses	—	1	—	—
Shampoos	—	24	—	0.0001–1
Tonics, dressings, etc.	2	12	>0.1–1	0.00001–0.01
Other	—	6	—	0.001[f]
Hair-coloring products				
Tints	—	1	—	—
Rinses	—	1	—	—
Color Sprays	—	1	—	—
Other	—	2	—	—
Makeup				
Blushers	2	11	≤0.1–1	0.01–0.1
Face powders	1	22	≤ 0.1	0.001–0.6
Foundations	7	42	≤ 0.1	0.02–0.6
Lipsticks	14	41	≤0.1–1	0.001–0.2
Makeup bases	1	15	≤ 0.1	0.01–0.3
Rouges	2		≤0.1–1	0.1
Makeup fixatives	—	1	—	0.01
Other	1	21	≤ 0.1	0.2–0.6

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TABLE 16
Historical and current cosmetic product uses and concentrations for Retinol and Retinyl Palmitate

Product category	1981uses (Elder 1987)	2002 uses (FDA 2002)	1981 concentrations (Elder 1987) (%)	2005 concentrations (CTFA 2005) (%)
Nail care products				
Cuticle softeners	—	3	—	0.001–0.1
Creams and lotions	1	4	≤ 0.1	—
Nail polishes and enamels	1	3	≤ 0.1	0.01–0.06
Nail care products				
Nail polish and enamel removers	—	—	—	0.1
Other	—	3	—	0.002
Personal hygiene products				
Other	—	1	—	0.001–0.1[g]
Shaving products				
Aftershave lotions	—	4	—	0.001–0.3
Shaving products				
Shaving cream (aerosol, brushless, and lather)	—	—	—	0.00001–0.01
Other	—	—	—	0.01
Skin care products				
Skin cleansing creams, lotions, liquids, and pads	—	24	—	0.0001–0.2
Depilatories	—	—	—	0.02
Face and neck creams, lotions, powder, and sprays	12[b]	37	≤0.1–1[b]	0.003–1.7
Body and hand creams, lotions, powder, and sprays		57		0.001–0.3
Foot powders and sprays	—	1	—	0.06
Moisturizers	28	110	≤0.1–1	0.006–0.6
Night creams, lotions, powder, and sprays	9	35	≤0.1–5	0.001–0.5
Paste masks/mud packs	4	24	≤0.1–1	0.06–0.4
Skin fresheners	—	3	—	0.001–0.02
Wrinkle smoothers (removers)	1	N/A[c]	>0.1–1	N/A[c]
Other	7	49	≤0.1–1	0.05–0.4
Suntan products				
Suntan gels, creams, liquids, and sprays	—	5	—	0.0001–0.1
Indoor tanning preparations	—	2	—	0.01–0.05
Other	1	8	>0.1–1	0.01
Total uses/ranges for Retinyl Palmitate	102	677	≤0.1–5	0.000001–1.7

[a]Body cleanser.
[b]These categories were combined when the original safety assessment was performed and are now two separate categories.
[c]No longer included as a cosmetic product category.
[d]Renewal serum.
[e]0.001% in a shower cream and 0.01% in a shower gel.
[f]Hot oil.
[g]0.0001% in a towelettes product.
[h]0.001% in a body oil.

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Sorbic Acid and Potassium Sorbate

CONCLUSION

In a safety assessment of Sorbic Acid and Potassium Sorbate (Elder, 1988), the CIR Expert Panel stated that these ingredients are safe as cosmetic ingredients in the present practices of use and concentration. Studies available since this safety assessment was completed, along with updated information regarding use in cosmetic products, were considered by the CIR Expert Panel. The Panel confirmed that Sorbic Acid and Potassium Sorbate are safe in the practices of use and concentrations given in Table 17 and did not reopen the safety assessment.

DISCUSSION

In 1986, Sorbic Acid and Potassium Sorbate were reported as being used in 445 products (at concentrations of $\leq$0.1% to 5%) and 117 products (at concentrations of), respectively, at concentrations of use of 0.1% to 5% and $\leq$ 0.1% to 1%, respectively (Elder 1988). Data provided to FDA in 2005 indicated that Sorbic Acid and Potassium Sorbate were being used in 411 and 300 products, respectively (FDA 2005). A survey in 2006 of industry use patterns reported that Sorbic Acid was being used in cosmetics at concentrations ranging from 0.00002% to 3.0% and that Potassium Sorbate was being used at concentrations ranging from 0.00003% to 0.3% (CTFA 2006).

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TABLE 17
Historical and current cosmetic product uses and concentrations for Sorbic Acid and Potassium Sorbate

Product category	1986 uses (Elder 1988)	2005 uses (FDA 2005)	1986 concentrations (Elder 1988) (%)	2006 concentrations (CTFA 2006) (%)
		Sorbic Acid		
Baby products	4[a]		≤0.1–1[a]	
Shampoos		1		—
Lotions, oils, powders, and creams		—		—
Other		1		—
Bath products	20[a]		≤0.1–1[a]	
Soaps and detergents		3		0.0001–0.1
Oils, tablets, and salts		—		0.00006
Bubble baths		12		0.2
Other		7		0.06
Eye makeup				
Eyeliners	12	1	≤0.1–1	0.1–0.2
Eye shadow	26	22	≤0.1–1	0.0004–0.3
Eye lotion	—	2	—	—
Eye makeup remover	8	5	≤0.1–1	0.3
Mascara	10	9	≤0.1–1	0.0002–0.2
Other	15	9	≤0.1–1	—
Fragrance products				
Colognes and toilet waters	—	—	—	0.001
Perfumes	—	—	—	0.2
Powders	14	1	≤0.1–1	0.3
Sachets	—	—	—	0.3
Other fragrance preparations	10	1	≤0.1–1	0.00006
Noncoloring hair products	25[a]		≤0.1–1[a]	
Conditioners		6		0.00002–0.009
Sprays/aerosol fixatives		1		0.15
Rinses		—		—
Tonics, dressings, etc.		8		0.3
Permanent waves		2		—
Shampoos (noncoloring)		7		0.2
Other		2		—
Hair-coloring products				
Dyes and colors	—	65	—	—
Tints	—	1	—	—
Shampoos	3	1	>0.1–1	—
Color sprays	—	2	—	—
Lighteners with color	—	2	—	—
Makeup				
Blushers	19	11	≤0.1–1	0.0006–0.3
Face powders	—	21	—	0.04–0.7
Foundations	13	37	≤0.1–1	0.05–0.3
Lipsticks	32	18	>0.1–1	0.2
Makeup bases	106	—	≤0.1–1	0.2
Rouges	4	—	≤0.1–1	—
Makeup fixatives	—	1	—	—
Other	21	16	≤0.1–1	0.07

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TABLE 17
Historical and current cosmetic product uses and concentrations for Sorbic Acid and Potassium Sorbate *(Continued)*

Product category	1986 uses (Elder 1988)	2005 uses (FDA 2005)	1986 concentrations (Elder 1988) (%)	2006 concentrations (CTFA 2006) (%)
Nail care products				
Cuticle softeners	—	1	—	—
Creams and lotions	—	1	—	—
Other	3	1	≤0.1–1	0.05–0.2
Oral hygiene products				
Mouthwashes and breath fresheners	—	3	—	—
Personal hygiene products	6[a]		≤ 0.1[a]	
Underarm deodorants		—		—
Douches		—		—
Feminine deodorants		—		0.2
Other		7		0.06
Shaving products				
Shaving cream	—	2	—	—
Other	—	2	—	—
Skin care products				
Skin cleansing creams, lotions, liquids, and pads	18	17	≤0.1–5	0.05–0.2
Face and neck creams, lotions, powder and sprays	21[a]	9	≤0.1–1[a]	0.003–0.1
Body and hand creams, lotions, powder and sprays		22		0.001
Moisturizers	23	19	≤0.1–5	0.0001–3.0
Night creams, lotions, powders and sprays	22	1	≤0.1–1	—
Paste masks/mud packs	—	11	—	—
Skin fresheners	—	3	—	0.08
Other	—	19	—	0.1–0.2
Suntan products	7[a]		≤0.1–1[a]	
Suntan gels, creams, liquids, and sprays		5		0.001–0.2
Indoor tanning preparations		12		—
Other		1		—
Total uses/ranges forSorbic Acid	445	411	≤0.1–5	0.00002–3.0
	Potassium Sorbate			
Baby products				
Shampoos	—	—	—	0.3
Bath products	4[a]		≤0.1–1[a]	
Oils, tablets, and salts		1		0.0004–0.08
Soaps and detergents		—		0.00005–0.5
Bubble baths		2		0.0001
Other		14		0.002–0.5
Eye makeup				
Eyeliner	—	4	—	0.03
Eye shadow	—	1	—	—
Eye lotions	—	1	—	0.2
Eye makeup remover	—	4	—	0.3
Mascara	—	13	—	0.01–0.2
Other	6	2	≤0.1–1	0.1
Fragrance products				
Colognes and toilet waters	—	—	—	0.05
Perfumes	—	—	—	0.0002

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TABLE 17
Historical and current cosmetic product uses and concentrations for Sorbic Acid and Potassium Sorbate *(Continued)*

Product category	1986 uses (Elder 1988)	2005 uses (FDA 2005)	1986 concentrations (Elder 1988) (%)	2006 concentrations (CTFA 2006) (%)
Powders	—	15	—	—
Other	—	5	—	0.0004
Noncoloring hair products				
Conditioners	7	10	≤0.1–1	0.00006–0.6
Sprays/aerosol fixatives	—	1	—	<0.0001
Permanent waves	—	—	—	0.2
Rinses	—	1	—	—
Shampoos	18	11	≤0.1–1	0.00006–030
Tonics, dressings, etc.	3	7	≤0.1–1	0.00003–0.5
Wave sets	12	2	≤0.1–1	—
Other	—	14	—	0.00006
Hair-coloring products				
Dyes and colors	—	31	—	0.05
Makeup				
Blushers	—	1	—	0.2
Face powders	—	6	—	0.06
Foundations	9	4	≤0.1–1	0.05–0.1
Lipsticks	—	1	—	0.2–0.3
Makeup bases	—	1	—	0.2–0.3
Rouges	—	1	—	—
Other	—	3	—	0.3
Nail care products				
Creams and lotions	—	—	—	0.0003
Nail polishes and enamels	—	—	—	0.0005
Oral hygiene products				
Dentifrices	—	—	—	0.0005
Mouthwashes and breath fresheners	—	—	—	0.3
Other	—	1	—	0.001
Personal hygiene products				
Underarm deodorants	—	2	—	0.00005–0.002
Other	—	4	—	0.07–0.5
Shaving products				
Aftershave lotions	—	15	—	0.002–0.1
Shaving cream (aerosol, brushless, and lather)	—	3	—	—
Other	—	1	—	0.002
Skin care products				
Skin cleansing creams, lotions, liquids and pads	7	19	≤0.1–1	0.001–0.3
Depilatories	—	2	—	—
Face and neck creams, lotions, powder, and sprays	51[a]	20	≤0.1–1[a]	0.0006–0.4
Body and hand creams, lotions, powder, and sprays		13		0.0002–0.4
Foot powders and sprays	—	—	—	0.0001
Moisturizers	—	22	—	0.08–0.22
Night creams, lotions, powder, and sprays	—	8	—	0.002–0.4
Paste masks/mud packs	—	10	—	0.0005
Skin fresheners	—	1	—	—
Other	—	19	—	0.01–0.1

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TABLE 17
Historical and current cosmetic product uses and concentrations for Sorbic Acid and Potassium Sorbate *(Continued)*

Product category	1986 uses (Elder 1988)	2005 uses (FDA 2005)	1986 concentrations (Elder 1988) (%)	2006 concentrations (CTFA 2006) (%)
Suntan products				
Suntan gels, creams, liquids, and sprays	—	1	—	0.2
Indoor tanning preparations	—	2	—	0.0002
Other	—	1	—	—
Total uses/ranges for Potassium Sorbate	117	300	≤0.1–1	0.00003–7.0

[a]These categories were combined when the original safety assessment was performed and are now two or more separate categories.
[b]0.002% to 0.4% for creams, lotions, and powders; 0.001% for sprays.

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Steareth-2, -4, -6, -7, -10, -11, -13, -15, and -20

CONCLUSION

In a safety assessment of Steareth-2, -4, -6, -7, -10, -11, -13, -15, and -20 (Elder 1988), the Cosmetic Ingredient Review (CIR) Expert Panel stated that these ingredients are safe as used in cosmetic products. The Expert Panel reviewed newly available studies since that assessment, along with updated information regarding types and concentrations of use. The Expert Panel confirmed the safety of Steareth-2, -4, -6, -7, -10, -11, -13, -15, and -20 in the practices of use and concentration, as given in Table 18 and determined to not reopen this safety assessment.

TABLE 18
Historical and current cosmetic product uses and concentrations for Steareth -2, -4, -6, -7, -10, -15, and -20

Product category	1981 uses (Elder 1988)	2005 uses (FDA 2006)	1981 use concentrations (Elder 1988) (%)	2003 use concentrations (CTFA 2006) (%)
		Steareth-2		
Baby care				
Lotions, oils, powders, and creams	—	3	—	2
Bath				
Oils, tablets, and salts	—	—	—	0.001
Soaps and detergents	—	—	—	0.004–2
Bubble baths	—	—	—	0.001
Other bath	—	—	—	0.001–2[c]
Eye makeup	42[a]		>0.1–5[a]	
Eyebrow pencils		—		0.1
Eye shadow		—		0.8–3
Eye lotions		1		0.5–2
Eye makeup remover		3		2
Mascara		2		0.5–2
Other eye makeup		1		3
Fragrances				
Colognes and toilet waters	—		—	0.0002
Other fragrances	—	3	—	—
Noncoloring Hair Care	19[a]	—	>0.1–1[b]	—
Conditioners		4		—
Straighteners		3		—
Rinses		1		—
Tonics, dressings, etc.		3		0.3–2
Other noncoloring hair care		4		0.5
Hair Coloring		—		—
Makeup	42[1]		>0.1–5[a]	
Blushers		—		0.2–1
Face powders		3		0.6
Foundations		23		0.4–3
Lipsticks		1		2
Makeup bases		5		0.2–2
Other makeup		5		0.2–3[d]
Nail care				
Cuticle softeners	—	—	—	2
Creams and lotions	—	1	—	—
Personal hygiene				
Underarm deodorants	—	—	—	2–4
Other	—	15	—	0.5
Shaving				
Aftershave lotions	—	9	—	1–6
Shaving cream	—	2	—	0.001
Skin care				
Cleansing creams, lotions, etc.	—	15	—	0.3–3
Depilatories	—	—	—	0.001
Face and neck skin care	46[c]	8	>0.1–25[c]	0.6–2
Body and hand skin care		49		0.004–3

(Continued on next page)

TABLE 18

Historical and current cosmetic product uses and concentrations for Steareth −2, −4, −6, −7, −10, −15, and −20 *(Continued)*

Product category	1981 uses (Elder 1988)	2005 uses (FDA 2006)	1981 use concentrations (Elder 1988) (%)	2003 use concentrations (CTFA 2006) (%)
Foot powders and sprays	—	3	—	2
Moisturizers	—	42	—	0.8–4
Night skin care	—	8	—	2–4
Paste masks/mud packs	—	5	—	—
Skin fresheners	—	1	—	—
Other skin care	—	16	—	2
Suntan	46[c]		>0.1–25[c]	
Suntan gels, creams, liquids and sprays		1		0.7–4
Indoor tanning		7		0.2–1
Other suntan		1		—
Total uses/ranges for Steareth-2	107	248	>0.1–25	0.0002–4
		Steareth-4		
Bath				
Soaps and detergents	—	8	—	0.1–0.5
Other bath	—	6	—	—
Noncoloring Hair Care				
Conditioners	—	—	—	0.6
Rinses	—	1	—	0.6
Shampoos	—	1	—	0.2–2
Skin Care				
Cleansing creams, lotions, etc.	—	3	—	—
Body and hand skin care	—	—	—	0.06
Total uses/ranges for Steareth-4	—	19	—	0.01–2
		Steareth-6		
Bath				
Oils, tablets, and salts	—	1	—	—
Skin Care				
Other skin care	—	1	—	—
Total uses/ranges for Steareth-6	—	2	—	—
		Steareth-7		
Skin Care				
Cleansing creams, lotions, etc.	—	1	—	—
Face and neck skin care	—	3	—	—
Body and hand skin care	—	2	—	—
Paste masks/mud packs	—	—	—	0.1
Total uses/ranges for Steareth-7	—	6	—	0.1
		Steareth-10[b]		
Eye makeup	24[a]	—	>0.1–5[a]	—
Eyeliners		—		0.4
Eye lotions		1		—
Mascara		2		1
Other eye makeup		—		0.009

(Continued on next page)

TABLE 18

Historical and current cosmetic product uses and concentrations for Steareth −2, −4, −6, −7, −10, −15, and −20 *(Continued)*

Product category	1981 uses (Elder 1988)	2005 uses (FDA 2006)	1981 use concentrations (Elder 1988) (%)	2003 use concentrations (CTFA 2006) (%)
Fragrance products	5[a]	—	>0.1–5[a]	—
Noncoloring hair care				
Conditioners	2	1	≤0.1–5	2
Straighteners	9	2	>0.1–5	0.4
Shampoos	2	—	>0.1–5	—
Tonics, dressings, etc.	5	—	>0.1–5	—
Other noncoloring hair care	—	—	—	0.1
Hair coloring				
Bleaches	2	—	>0.1–5	—
Makeup	24[a]		>0.1–5[a]	
Foundations		1		—
Lipsticks		—		0.5
Makeup fixatives		1		—
Oral hygiene				
Mouthwashes and breath freshener sprays	5	—	>0.1–5	—
Personal hygiene				
Underarm deodorants	2	—	>0.1–5	—
Other personal hygiene	19	—	≤0.1–5	—
Shaving				
Aftershave lotions	5	—	>0.1–5	—
Skin care				
Cleansing creams, lotions, etc.	7	1	>0.1–5	0.2
Face and neck skin care	29[a]	3	>0.1–5[a]	0.5–1
Body and hand skin care		2		2
Foot powders and sprays	—	1	—	—
Moisturizers	—	18	—	1–2
Night skin care	—	1	—	—
Paste masks/mud packs	—	—	—	0.1
Other skin care	—	3	—	—
Suntan	29[a]		>0.1–5[a]	
Suntan gels, creams, liquids and sprays		1		—
Indoor tanning		—		—
Other suntan		—		—
Total uses/ranges for Steareth-10	104	38	≤0.1–5	0.009–3
	Steareth-15[b]			
Eye Makeup	24	—	>0.1–5	—
Fragrances	5	—	>0.1–5	—
Colognes and toilet waters	—	1	—	—
Noncoloring Hair Care				
Conditioners	2	—	≤0.1–5	—
Straighteners	9[a]	—	>0.1–5[a]	—
Permanent waves		—		—
Shampoos	2	—	>0.1–5	—
Tonics, dressings, etc.	5	—	>0.1–5	—

(Continued on next page)

TABLE 18
Historical and current cosmetic product uses and concentrations for Steareth −2, −4, −6, −7, −10, −15, and −20 *(Continued)*

Product category	1981 uses (Elder 1988)	2005 uses (FDA 2006)	1981 use concentrations (Elder 1988) (%)	2003 use concentrations (CTFA 2006) (%)
Hair coloring				
Bleaches	2	—	>0.1–5	—
Makeup	24	—	>0.1–5	—
Oral hygiene				
Mouthwashes and breath freshener sprays	5	—	>0.1–5	—
Personal hygiene				
Underarm deodorants	2	—	>0.1–5	—
Other personal hygiene	19	—	≤0.1–5	—
Shaving				
Aftershave lotions	5	—	>0.1–5	—
Skin care				
Cleansing creams, lotions, etc.	7	—	>0.1–5	—
Face and neck skin care	29[a]	—	>0.1–5[a]	—
Body and hand skin care		—		—
Suntan				
Suntan gels, creams, liquids and sprays	29[a]	—	>0.1–5[a]	—
Indoor tanning		—		—
Other suntan		—		—
Total uses/ranges for Steareth-15	104	1	≤0.1–5	—
	Steareth-20[b]			
Bath				
Soaps and detergents	—	1	—	0.006–2
Other bath	—	14	—	0.2
Eye makeup	24[a]	—	>0.1–5[a]	—
Eyeliners		—		0.3
Eye lotions		1		0.4–0.9
Eye makeup remover		1		0.2–1
Mascara		3		—
Other eye makeup		2		—
Fragrances	5[a]		>0.1–5[a]	
Other fragrances		3		—
Noncoloring hair care				
Conditioners	2	7	≤0.1–5	—
Straighteners	9[a]	3	>0.1–5[a]	0.4
Permanent waves		3		—
Shampoos	2	—	>0.1–5	—
Tonics, dressings, etc.	5	5	>0.1–5	4–15
Other noncoloring hair care	—	6	—	—
Hair coloring				
Bleaches	2	—	>0.1–5	—
Makeup	24[a]		>0.1–5[a]	
Foundations		4		0.6
Lipsticks		—		—
Makeup bases		21		2

(Continued on next page)

TABLE 18
Historical and current cosmetic product uses and concentrations for Steareth −2, −4, −6, −7, −10, −15, and −20 *(Continued)*

Product category	1981 uses (Elder 1988)	2005 uses (FDA 2006)	1981 use concentrations (Elder 1988) (%)	2003 use concentrations (CTFA 2006) (%)
Other makeup		2		—
Nail care				
Creams and lotions	—	—	—	0.8
Other nail care	—	1	—	—
Oral hygiene				
Mouthwashes and breath freshener sprays	5	—	>0.1	—
Personal hygiene				
Underarm deodorants	2	2	>0.1–5	0.6–4
Other personal hygiene	19	—	≤0.1–5	—
Shaving				
Aftershave lotions	5	—	>0.1–5	3
Shaving cream	—	1	—	—
Skin Care				
Cleansing creams, lotions, etc.	7	7	>0.1–5	0.2–4
Face and neck skin care	29[a]	4	>0.1–5[a]	0.2–1
Body and hand skin care		60		0.2–3
Foot powders and sprays	—	2	—	2
Moisturizers	—	33	—	0.04–4
Night skin care	—	1	—	0.09
Paste masks/mud packs	—	3	—	—
Other	—	7	—	0.5–1
Suntan	29[a]		>0.1–5[a]	
Suntan gels, creams, liquids, and sprays		—		3
Indoor tanning		7		0.2–1
Other suntan		1		—
Total uses/ranges for Steareth-20	104	205	≤0.1–5	0.006–15

[a]These categories were combined when the original safety assessment was performed and are now two or more separate categories.
[b]Steareth-10, -15, and -20 were combined in the original safety assessment, so no separate usage or use concentration data were available; available data are repeated for each of −10, −15, and −20.
[c]Body scrub: 0.001%, 2%.
[d]Concealer: 0.2%.

Steareth-2 was used in 107 cosmetic products in 1981, based on voluntary reports provided to FDA by industry with concentrations ranging from >1% to 25% (Elder 1988). In 2005, Steareth-2 was reportedly used in 248 cosmetic products (FDA 2006). Data from an industry survey in 2006 indicated that Steareth-2 was used at concentrations ranging from 0.002% to 4% (CTFA 2006).

Steareth-4 was not used in 1981, based on voluntary reports provided to FDA by industry (Elder 1988). In 2005, Steareth-4 was reportedly used in 19 cosmetic products (FDA 2006). Data from an industry survey in 2006 indicated that Steareth-4 was used at concentrations ranging from 0.01% 2% (CTFA 2006).

Steareth-6 was not used in 1981, based on voluntary reports provided to FDA by industry (Elder 1988). In 2005, Steareth-6 was reportedly used in 2 cosmetic products (FDA 2006). Data from an industry survey in 2006 indicated that Steareth-6 was used at 0.1% (CTFA 2006).

Steareth-7 was not used in 1981, based on voluntary reports provided to FDA by industry (Elder 1988). In 2005, Steareth-7 was reportedly used in 6 cosmetic products (FDA 2006). Data from an industry survey in 2006 included no use concentration data for Steareth-7 (CTFA 2006).

Steareth-10, -15, and -20 were combined in the original safety assessment, so no separate usage or use concentration data were available. Combined, this group was used in 104 cosmetic products in 1981, based on voluntary reports provided to FDA by industry with concentrations ranging from ≤01% to 5% (Elder 1988). In 2005, Steareth-10 was reportedly used in 38 cosmetic

products (FDA 2006). Data from an industry survey in 2006 indicated that Steareth-10 was used at concentrations ranging from 0.009% to 3% (CTFA 2006). In 2005, Steareth-15 was reportedly used in one cosmetic product (FDA 2006). Data from an industry survey in 2006 included no use concentration data for Steareth-15 (CTFA 2006). In 2005, Steareth-20 was reportedly used in 205 cosmetic product (FDA 2006). Data from an industry survey in 2006 indicated that Steareth-20 was used at concentrations ranging from 0.006% to 15% (CTFA 2006).

There were no reports of uses of Steareth-11 or Steareth-13 in 1981 (Elder 1988) or in 2005 (FDA 2006), nor did the recent industry survey uncover any use concentrations (CTFA 2006).

The CIR Expert Panel recognized that there are data gaps regarding use and concentration of these ingredients. However, the overall information available on the types of products in which these ingredients are used and at what concentrations indicate a pattern of use, which was considered by the Expert Panel in assessing safety.

These ingredients, in the form of liposomes, can enhance the penetration of other ingredients through the skin (e.g., HC Yellow No. 4, Disperse Yellow 3). The Panel cautioned that care should be taken in formulating cosmetic products that may contain these ingredients in combination with any ingredients whose safety was based on their lack of dermal absorption data, or when dermal absorption was a concern.

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Tallow, Tallow Glyceride, Tallow Glycerides, Hydrogenated Tallow Glyceride, and Hydrogenated Tallow Glycerides

CONCLUSION

In a safety assessment of Tallow, Tallow Glyceride, Tallow Glycerides, Hydrogenated Tallow Glyceride, and Hydrogenated Tallow Glycerides (Elder 1990), the Cosmetic Ingredient Review (CIR) Expert Panel stated that these ingredients are safe as (then) used in cosmetic products. The Expert Panel reviewed newly available studies since that assessment, along with updated information regarding types and concentrations of use. The Panel determined to not reopen this safety assessment. Therefore, the Panel confirms that Tallow, Tallow Glyceride, Tallow Glycerides, Hydrogenated Tallow Glyceride, and Hydrogenated Tallow Glycerides are safe as cosmetic ingredients in the practices of use and concentration, as given in Table 19.

DISCUSSION

The Panel was concerned with the dangers inherent in using human or animal-derived ingredients, namely the transmission of infectious agents. The CIR Expert Panel stressed that these ingredients must be free of detectable pathogenic viruses or infectious agents (e.g., bovine spongiform encephalopathy (BSE) prions). Suppliers and users of these ingredients must accept responsibility for assuring that these ingredients are risk-free.

TABLE 19
Historical and current cosmetic product uses and concentrations for Tallow, Tallow Glyceride, Tallow Glycerides, Hydrogenated Tallow, Hydrogenated Tallow Glyceride, and Hydrogenated Tallow Glycerides

Product category	1984 uses (Elder 1990)	2005 uses (FDA 2005)	1984 concentrations (Elder 1990) (%)	2006 concentrations (CTFA 2006) (%)
	Tallow			
Baby products				
Other	2	2	10–25, >50	—
Bath products				
Soaps and detergents	14	25	10–25, >50	78
Other	1	1	5–10	—
Noncoloring hair care products				
Straighteners	—	1	—	—
Shampoos	1	2	5–10	—
Makeup				
Foundations	1	—	1–5	—
Shaving products				
Shaving soap	1	—	25–50	—
Skin care products				
Moisturizers	1	—	1–5	—
Other	1	1	10–25	—
Total uses/ranges for Tallow	22	32	1–>50	78
	Tallow Glyceride			
Eye makeup				
Eyebrow pencils	10	1	10–25	—
Eyeliners	—	13	—	—
Eye shadow	1	—	10–25	—
Other	1	—	5–10	—
Makeup				
Lipsticks	12	7	10–25	—
Other	—	1	—	—
Total uses/ranges for Tallow Glyceride	24	22	5–25	—
	Tallow Glycerides			
Eye makeup				
Eyeliners	2	7	5–25	—
Eye shadow	—	7	—	—
Other	—	1	—	—
Hair coloring products				
Other	—	1	—	—
Skin care products				
Face and neck creams, lotions, powder, and sprays	1[a]	—	5–10[a]	—
Body and hand creams, lotions, powder, and sprays		—		—
Moisturizers	1	—	5–10	—
Other	1	—	—	—
Total uses/ranges for Tallow Glycerides	73	6	5–25	10–18
Makeup				
Foundations	—	—	—	1
Lipsticks	3	5	0.1–5	—
Makeup bases	1	1	1–5	—
Other	—	1	—	9[b]

(Continued on next page)

TABLE 19

Historical and current cosmetic product uses and concentrations for Tallow, Tallow Glyceride, Tallow Glycerides, Hydrogenated Tallow, Hydrogenated Tallow Glyceride, and Hydrogenated Tallow Glycerides *(Continued)*

Product category	1984 uses (Elder 1990)	2005 uses (FDA 2005)	1984 concentrations (Elder 1990) (%)	2006 concentrations (CTFA 2006) (%)
Eye makeup				
Eyeliners	2	7	5.25	—
Eyeshadow	—	7	—	—
Other	—	1	—	—
Makeup				
Foundations	—	—	—	1
Lipsticks	3	5	0.1–5	—
Makeup bases	1	1	1–5	—
Other	—	1	—	9[b]
Hydrogenated Tallow Glyceride				
Skin care products				
Skin cleansing creams, lotions, liquids, and pads	2	3	1–5	—
Face and neck creams, lotions, powder, and sprays	2[a]	—	1–5[a]	—
Body and hand creams, lotions, powder, and sprays		4		—
Moisturizers	1	5	1–5	—
Other	—	3	—	—
Suntan products				
Other	1	—	0.1–1	—
Total uses/ranges for Hydrogenated Tallow Glyceride	12	37	0.1–25	1–9
Hydrogenated Tallow Glycerides				
Eye makeup				
Eyebrow pencils	3	—	1–10	—
Eyeliners	3	2	1–10	—
Eye shadow	2	—	5–10	—
Other	2	—	5–10	—
Makeup				
Blushers	1	—	—	—
Lipsticks	18	43	0.1–5	14
Makeup bases	1	—	—	—
Other	12	—	5–25	—
Skin care products				
Skin cleansing creams, lotions, liquids, and pads	1	—	—	—
Face and neck creams, lotions, powder, and sprays	4[a]	—	0.1–10[a]	—
Body and hand creams, lotions, powder, and sprays		—		—
Moisturizers	—	1	—	—
Night creams, lotions, powder and sprays	3	—	0.1–1, 5–10	—
Total uses/ranges for Hydrogenated Tallow Glycerides	50	46	0.1–25	14

[a]These categories were combined when the original safety assessment was performed and are now two separate categories.
[b]9% reported in a lip pencil.

Tests to assure the absence of a pathogenic agent in the ingredients or controls to assure derivation from pathogen-free sources are two approaches that should be considered.

A new FDA regulation has been promulgated regarding Tallow and its derivatives in cosmetic applications, in response to the increase of transmissible spongiform encephalopathies (TSE) from ingestion of meat products from infected livestock, as follows:

> Use of prohibited cattle materials in cosmetic products... Prohibited cattle materials means specified risk materials, small intestine of all cattle, material from non-ambulatory disabled cattle, material from cattle not inspected and passed or MS (Beef). Prohibited cattle materials do not include tallow that contains no more than 0.15% hexane-insoluble impurities and tallow derivatives...Tallow must be free of prohibited cattle risk material or must contain not more than 0.15% hexane-insoluble impurities determined by the method for "hexane-insoluble matter"(CFR 21 §700.27).

The European Union (2005) has also announced a ruling on Tallow and its derivatives for use in cosmetic ingredients:

> Tallow derivatives may be used provided that the following methods have been used and strictly certified by the producer: (1) transesterification or hydrolysis at at least 200°C and at an appropriate corresponding pressure for 20 minutes (for glycerol, fatty acids, and fatty acid esters), and (2) saponification with NaOH 12M (for glycerol and soaps) using either the batch process at 95°C for 3 hours or the continuous process at 140°C, two bars (2000 hPa) for 8 minutes or equivalent conditions.

Because of the manner that Tallow and its derivative are rendered and processed, no BSE agents are expected to be found in cosmetics containing these ingredients.

According to Elder (1990), Tallow was used in a total of 22 cosmetic products while Tallow Glyceride and Tallow Glycerides were used in 24 and 73 cosmetic products, respectively. Hydrogenated Tallow Glyceride and Hydrogenated Tallow Glycerides were used in 12 and 50 formulations, respectively. Uses reported by industry to the FDA in 2005 are 32, 22, 6, 37, and 46 for Tallow, Tallow Glyceride, Tallow Glycerides, Hydrogenated Tallow Glyceride, and Hydrogenated Tallow Glycerides, respectively.

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