Addendum to the Final Report on the Safety Assessment of PEGs Lanolin to Include PEG-5, -10, -24, -25, -35, -55, -100, and -150 Lanolin; PEG-5, -10, -20, -24, -30, and -70 Hydrogenated Lanolin; PEG-75 Lanolin Oil; and PEG-75 Lanolin Wax[1]

The safety of selected polyethylene glycols (PEGs) Lanolin polymers was previously reviewed. This review completes the safety assessment of all the PEGs Lanolin polymers and related cosmetic ingredients. PEGs Lanolin are prepared by ethoxylating the hydroxy fatty acids, hydroxy esters, sterols, and alcohols present in whole lanolin. The number of moles of ethylene oxide reacted with each respective lanolin component corresponds to the average polyethylene glycol chain length. PEGs Lanolins, PEGs Hydrogenated Lanolins, PEG Lanolin Oil, and PEG Lanolin Wax are used as emulsifying, soluhilizing, and cleansing agents. PEGs Hydrogenated Lanolins are also hair-conditioning agents and skin-conditioning emollients. Few data on the PEGs Lanolin were available regarding systemic toxicity, mutagenicity, carcinogenicity, and clinical safety. Related compounds including PEGs, Lanolin, and Lanolin Oil have been previously reviewed. Based on clinical data in burn patients, PEGs were mild irritants/sensitizers and there was evidence of nephrotoxicity. No such effects were seen in animal studies on intact skin. Cosmetic manufacturers should continue to adjust product formulations to minimize any untoward effects when products are used on damaged skin. No evidence of phototoxic effects was found in clinical studies. Comedogenic effects have resulted from the use of cosmetic products containing lanolin compounds. No evidence of mutagenicity, carcinogenicity, or reproductive and developmental toxicity was found with these related compounds. Although metabolites of ethylene glycol monoalkyl ethers are reproductive and developmental toxins, it was considered unlikely that the relevant metabolites would be found in or produced from the use of PEGs Cocamine in cosmetic formulations. Based primarily on data from ingredients with related structures, it was concluded that PEG-S, -10, -24, -25, -35, -55, -100, and -150 Lanolin; PEG-S, -10, -20, -24, -30, and -70 Hydrogenated Lanolin; PEG-75 Lanolin Oil; and PEG-75 Lanolin Wax are safe for use in cosmetic formulations under the present practices of use.

INTRODUCTION

The following report is an addendum to the safety assessment of polyethylene glycol (PEG)-20, -27, -30, -40, -50, -60, -75, and -85 Lanolin. In the earlier safetyassessment, the Cosmetic Ingredient Review (CIR) Expert Panel concluded that these PEGs Lanolin were safe as presently used in cosmetic products (Elder 1982).

Additional ingredients being reviewed are PEG-5, -10, -24, -25, -35, -55, -85, -100, and -150 Lanolin; PEG-5, -10, -20, -24, -30, and -70 Hydrogenated Lanolin; PEG-75 Lanolin Oil; and PEG-75 Lanolin Wax. These ingredients are used in cosmetics as surfactants and as hair- and skin-conditioning agents. Note that the different chain length PEGs are formed by condensing ethylene oxide and water, with the average number of moles of ethylene oxide used corresponding to the number in the name.

The basic chemical components of these ingredients have been reviewed previously by the CIR Expert Panel and Final Reports have been published. The following conclusions were made:

> PEG-6, -8, -32, -75, 150, -14M, and -20M are safe for use at the concentrations reflected in the Cosmetic Use section and in the product formulation safety test data included in the Final Report. The Expert Panel recommends that cosmetic formulations containing these PEGs not be used on damaged skin (Andersen 1993).
>
> Lanolin. Lanolin Oil. Lanolin Wax. Lanolin Acid. Lanolin Alcohol, Acetylated Lanolin, Acetylated Lanolin Alcohol, Hydrogenated Lanolin, and Hydroxylated Lanolin are safe for topical application (Elder 1980).

Because there are limited data available specifically on the PEG derivatives of the lanolin group of chemicals, the relevant data from the Final Reports on the PEG group of chemicals and lanolin and its derivatives have been summarized in this review as a basis for the assessment of safety of the additional PEGs Lanolin compounds.

CHEMISTRY

Definition

PEG-5, -10, -20, -24, -25, -27, -30, -35, -40, -50, -55, -60, -75, -85, -100, and -150 Lanolin (CAS No. 61790-81-6 [generic]) are the polyethylene glycol derivatives of whole lanolin (q.v.) with an average number of moles of ethylene oxide equal to the number in the name. PEG-5, -10, -20, -24, -30, and -70 Hydrogenated Lanolin (CAS No. 68648-27-1 [generic]) are polyethylene glycol derivatives of hydrogenated lanolin (q.v.) with an average number of moles of ethylene oxide equal to the number in the

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name (n). PEG-75 Lanolin Oil (CAS No. 68648-38-4 [generic]) and PEG-75 Lanolin Wax are polyethylene glycol derivatives of lanolin oil (q.v.) and lanolin wax (q.v.), respectively, with an average of 75 moles of ethylene oxide (Wenninger and McEwen 1997).

Lanolin is the purified secretory product of sheep sebaceous glands (Elder 1982). Lanolin typically is composed of 35.4% esters of sterols and triterpene alcohols; 23.7% esters of aliphatic alcohols; 20% monohydroxy esters of sterols, triterpene alcohols, or aliphatic alcohols; 7.9% di- and polyhydroxyesters and free diols; 5.6% free aliphatic alcohols, 4.1% free sterols; 0.6% free hydrocarbons; 0.5% free fatty acids; and 2.2% unknowns (Elder 1982).

Physical and Chemical Properties

PEGs Lanolin are partially soluble in water and/or alcohol and may be completely miscible in polar solvents. As the oxyethylene chain length increases, water and alcohol solubilities and surface activities also increase and emulsification decreases; there is no loss of emolliency. PEG-75 Lanolin is a viscous, semisolid, cream-colored, wax-like material with a slight odor. PEG-60 Lanolin has a melting range of 46–54°C. A 5% aqueous solution of PEG-30 Lanolin has been reported to have a pH of 4–7 (Elder 1982).

Method of Manufacture

PEGs Lanolin are prepared by ethoxylating the hydroxy fatty acids, hydroxy esters, sterols, and alcohols present in whole lanolin. An average of n moles ethylene oxide are added to each equivalent of lanolin in the presence of an alkaline catalyst. A typical reaction of a hydroxy lanolin ester with n moles of ethylene oxide is shown in Figure 1 (Elder 1982).

Impurities

A maximum of 2.5% inorganic salts has been found in PEG-75 Lanolin. Trace amounts of 1,4-dioxane, a by-product of the ethoxylation process, may be present in PEGs Lanolin. Pesticides and trace metals found in crude lanolin may also be impurities (Elder 1982).

Silverstein et al. (1984) reported that PEG-6 may contain small amounts of monomer and dimers. The amounts were not quantified. Peroxides, formed as a result of autoxidation, are found in PEG-32 and PEG-75 (Hamburger, Azaz, and Donbrow 1975). The amount of peroxide in PEGs is dependent upon the molecular weight of the PEG and its age. The older the compound, the greater the concentration of peroxides. In a colorimetric assay used to determine the peroxide concentrations in several production lots of PEGs, PEG-6 and PEG-8 were each added to acidified potassium iodide solution, and the iodine liberated was titrated against a standard thiosulfate solution. PEG-6 had peroxide concentrations ranging from 1.4 to 9.3 μEq thiosulfate/ml glycol. PEG-8 had concentrations ranging from 3.24 to 5.7 μEq thiosulfate/ml glycol. The specific peroxides present in the PEGs were not determined, but they were thought to be organic peroxides rather than hydrogen peroxide (McGinity, Hill, and La Via 1975).

Ethoxylated surfactants may also contain 1,4-dioxane, a by-product of ethoxylation (Robinson and Ciurczak 1980). 1,4-Dioxane is a known animal carcinogen (Kociba et al. 1974; Hoch-Ligeti, Argus, and Arcos 1970; Argus, Arcos, and Hoch-Ligeti 1965). In the CIR safety assessment of the PEG-Stearates, the cosmetic industry reported that it is aware that 1,4-dioxane may be an impurity in PEGs and, thus, uses additional purification steps to remove it from the ingredient before blending into cosmetic formulations (Elder 1983).

USE

Cosmetic

The PEGs Lanolin are surfactants used as emulsifying, solubilizing, and cleansing agents, and the PEG Hydrogenated Lanolins are hair-conditioning agents, skin-conditioning agents used as emollients, and surfactants used as emulsifying, solubilizing, and cleansing agents. PEG-75 Lanolin Oil and PEG-75 Lanolin Wax are also surfactants used for their cleansing, solubilizing, and emulsifying properties (Wenninger and McEwen 1997). The product formulation data submitted to the Food and Drug Administration (FDA) in 1995 indicated that these ingredients were used in a total of 238 products (Table 1) (FDA 1995). The Cosmetic, Toiletry, and Fragrance Association (CTFA) in 1995 reported that nail and cuticle products and hair moisturizer contained 5% and 2% PEG Lanolin Oil, respectively. A concentration of 0.5% PEG-75 Lanolin was used in waving lotion, and 0.30% PEG-60 Lanolin was used in eye makeup remover (CTFA 1995).

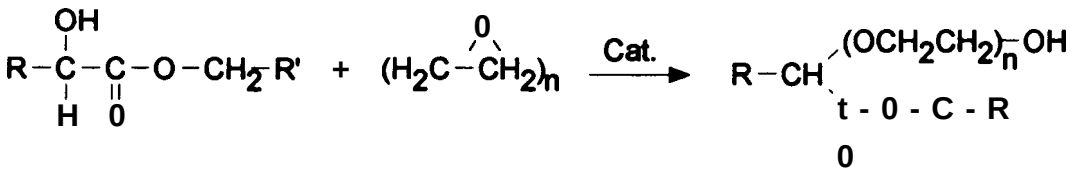

FIGURE 1
Typical reaction to produce PEGs Lanolin. Hydroxy lanolin ester (R = lanolin hydroxyacids and R′ = lanolin alcohols) reacting with n moles of ethylene oxide in the presence of an alkaline catalyst.

TABLE 1
Cosmetic product formulation data (FDA 1995)

Product category	Total no. formulations in category	Total no. of formulations containing ingredient
PEG-S Lanolin		
Hair conditioners	693	2
Rinses (noncoloring)	57	1
Shampoos (noncoloring)	916	5
Tonics, dressings, and other hair grooming aids	624	1
1995 total		**9**
PEG-20 Lanolin		
Eyeliner	588	1
Eye shadow	597	1
Body and hand preparations (excluding shaving preparations)	987	1
Night preparations	220	1
1995 total		**4**
PEG-24 Lanolin		
Rinses (noncoloring)	57	1
Body and hand preparations (excluding shaving preparations)	987	1
Indoor tanning preparations	62	1
1995 total		**3**
PEG-25 Lanolin		
Body and hand preparations (excluding shaving preparations)	987	1
1995 total		1
PEG-27 Lanolin		
Eyeliner	588	1
Eye shadow	597	3
Hair conditioners	693	2
Permanent waves	423	1
Other hair preparations	382	2
Other personal cleanliness products	317	1
Shaving cream	152	1
1995 total		**11**
PEG-30 Lanolin		
Other fragrance preparations	158	2
Aftershave lotion	236	1
Other shaving preparation products	60	2
Body and hand preparations (excluding shaving preparations)	987	1
Moisturizing preparations	873	1
Skin fresheners	228	1
1995 total		**8**
PEG-40 Lanolin		
Eyeliner	588	1
Shampoo (noncoloring)	916	1
Wave sets	104	1
1995 total		**3**
PEG-50 Lanolin		
Hair conditioners	693	1
Hair straighteners	59	3

(Continued on next page)

TABLE 1
Cosmetic product formulation data (FDA 1995) ***(Continued)***

Product category	Total no. formulations in category	Total no. of formulations containing ingredient
Other personal cleanliness products	317	1
Cleansing preparations	771	1
1995 total		**6**
PEG-60 Lanolin		
Other baby products	30	5
Hair straighteners	59	8
Hair dyes and colors (requiring caution statement and patch test instructions)	1437	1
Other personal cleanliness products	317	4
Body and hand preparations (excluding shaving preparations)	987	1
1995 total		**19**
PEG-75 Lanolin		
Baby lotions, oils, powders, and creams	57	1
Other baby products	30	9
Bath oils, tablets, and salts	146	1
Other bath preparations	144	1
Eye makeup remover	89	1
Hair conditioners	693	12
Hair spray (aerosol fixatives)	348	2
Hair straighteners	59	17
Permanent waves	423	9
Rinses (noncoloring)	57	2
Shampoos (noncoloring)	916	8
Tonics, dressings, and other hair grooming aids	624	16
Wave sets	104	1
Other hair preparations	382	3
Hair shampoos (coloring)	19	1
Other hair coloring preparations	79	5
Blushers (all types)	283	1
Foundations	333	1
Bath soaps and detergents	339	2
Feminine hygiene products	7	2
Other personal cleanliness products	317	10
Aftershave lotion	236	1
Cleansing preparations	771	7
Face and neck preparations (excluding shaving preparations)	261	1
Body and hand preparations (excluding shaving preparations)	987	3
Moisturizing preparations	873	1
Paste masks (mud packs)	276	1
Skin fresheners	228	4
Other skin care preparations	782	2
Indoor tanning preparations	62	1
Other suntan preparations	62	1
1995 total		**127**
PEG-85 Lanolin		
Bubble baths	204	1
Shampoos (noncoloring)	916	1

TABLE 1
Cosmetic product formulation data (FDA 1995) ***(Continued)***

Product category	Total no. formulations in category	Total no. of formulations containing ingredient
Other hair preparations	382	2
Cuticle softeners	25	1
Nail polish and enamel removers	33	1
1995 total		**6**
PEG-100 Lanolin		
Cleansing products	771	1
1995 total		**1**
PEG-75 Lanolin Oil		
Other bath preparations	144	1
Hair conditioners	693	1
Hair sprays (aerosol fixatives)	348	3
Hair straighteners	59	2
Permanent waves	423	1
Tonics, dressings, and other hair grooming aids	624	7
Wave sets	104	1
Other hair preparations	382	8
Nail polish and enamel removers	33	1
Other manicuring preparations	79	1
Bath soaps and detergents	339	2
Skin fresheners	228	1
1995 total		**29**
PEG-20 Hydrogenated Lanolin		
Hair straighteners	59	6
Tonics dressings, and other hair grooming aids	624	1
1995 total		**7**
PEG-24 Hydrogenated Lanolin		
Eye makeup remover	89	2
Hair conditioners	693	1
1995 total		**3**
PEG-30 Hydrogenated Lanolin		
Face and neck preparations (excluding shaving preparations)	261	1
1995 total		1

ANIMAL TOXICOLOGY

Results of toxicity studies with rats, rabbits, and dogs indicate that PEGs have low oral and dermal toxicity. In general, the greater molecular weight PEGs appear to be less toxic than the lighter weight PEGs in oral studies. Acute oral LD50s for PEGs in rabbits were 17.3 g/kg (100% PEG-6) and 76 g/kg (100% PEG-75). In subchronic, 90-day oral toxicity studies involving groups of albino rats, the largest (PEG-20M) and smallest (PEG-6) molecular weight PEGs tested did not induce toxicity or death when administered daily at concentrations of 4% or less; PEG-20M was administered in the diet and PEG-6 in drinking water. Toxic effects also were not observed in groups of dogs that received PEG-8, PEG-32, and PEG-75 at concentrations of 2% in the diet for one year. In acute dermal toxicity studies, no deaths were reported in groups of rabbits dosed with undiluted PEG-6 (20 ml/kg) or 40% PEG-20M (20 ml/kg). In other dermal toxicity studies, no evidence of toxicity was observed in a group of rabbits that received daily applications of PEG-6 5 days per week (2 ml/kg/day) for 18 weeks, or in rabbits that received daily applications of PEG-20M (0.8 g/kg/day) for 30 days; transient, mild erythema was observed in the 30-day study. The only evidence of systemic toxicity that resulted from dermal exposure was renal failure in rabbits that received repeated applications of an antimicrobial cream containing 63% PEG-6, 5% PEG-20, and 32% PEG-75 to excised skin sites for 7 days (Andersen 1993).

The acute oral and dermal toxicity of lanolin and its derivatives in rats was low. The acute oral LD50s for undiluted Lanolin and undiluted Lanolin Oil were >64 cc/kg and 46.5 cc/kg, respectively. The acute dermal LD50 for Lanolin Oil in rabbits was >10 ml/kg (Elder 1980).

Dermal Irritation and Sensitization

The PEGs were not irritating to the skin of rabbits or guinea pigs, and PEG-75 was not a sensitizer. In skin irritation tests, undiluted PEG-6 was applied to the skin of rabbits for 4 hours and 50% PEG-75 was applied to guinea pigs for 4 days and to rabbits over a 13-week period. In the guinea pig skin sensitization test, PEG-75 was tested at a concentration of 0.1% (Andersen 1993).

With one exception, lanolin and its derivatives were either nonirritating or, at most, mildly irritating to the skin of rabbits when tested at 100% concentrations. The exception was lanolin acid, which was a mild skin irritant. It was noted that lanolin acid is seldom, if at all, found in cosmetic formulations as the free acid (Elder 1980).

Ocular Irritation

PEGs -6 and -75 did not cause corneal injuries when instilled (undiluted, 0.5 ml) into the conjunctival sacs of rabbits. PEG-8 (35% solution, 0.1 ml) and PEG-32 (melted in water bath, 0.1 ml) induced mild ocular irritation in rabbits (Andersen 1993).

With the exception of lanolin acid (undiluted), lanolin and its derivatives (all undiluted) were either nonirritating or, at most, mildly irritating to the eyes of rabbits. Lanolin acid (undiluted) caused mild to moderately severe irritation (Elder 1980).

REPRODUCTIVE AND DEVELOPMENTAL TOXICITY

Ethylene Clycol and Its Ethers

It is generally recognized that the PEG monomer, ethylene glycol, and certain of its monoalkyl ethers (e.g., methoxyethanol, a.k.a. ethylene glycol monomethyl ether) are reproductive and developmental toxins. The CIR Expert Panel undertook a separate, limited scope review of these compounds in order to assess the possibility that PEG-derived cosmetic ingredients could present similar concerns (CIR 1996). In summary, this report concluded that the ethylene glycol monoalkyl ethers are not themselves toxic, but rather that one or more alcohol or aldehyde dehydrogenase metabolites are toxic. From the available data, the report also concluded that the toxicity of the monoalkyl ethers is inversely proportional to the length of the alkyl chain (methyl is more toxic than ethyl than propyl than butyl, etc.).

Given the methods of manufacture of the PEGs Lanolin and their derivatives, there is no likelihood of methoxyethanol, ethoxyethanol, etc., being present as an impurity. Although the exact structures of lanolin, hydrogenated lanolin, lanolin oil, and lanolin wax are not known, such extracts are usually long-chain compounds. When combined via an ether linkage with polyethylene glycol, it is not likely that any of the Lanolin compounds would present the simple R-group appearance of methyl, ethyl, propyl, or even butyl. It is unlikely that the Lanolin moieties would be metabolized (e.g., via β-oxidation) to simple methyl, ethyl, etc., alkyl groups. In addition, most of the polyethylene glycol chain lengths used in making the various PEGs Lanolin are 10 or longer, suggesting that there would be very little monomer linked by an ether group to the Lanolin moiety. The Expert Panel concluded that no reproductive or developmental hazard is posed by these compounds.

Polyethylene Glycol

No adverse reproductive effects occurred during subchronic (90 days) and chronic (2 years) oral toxicity studies of PEG-6-32 and PEG-75. In the subchronic study, PEG-75 was tested at a dose of 0.23 g/kg/day. In the chronic study, PEG-75 was tested at doses up to 0.062 g/kg/day and PEG-6-32 at doses up to 1.69 g/kg/day (Andersen 1993).

MUTAGENICITY

PEG-8 was negative in the Chinese hamster ovary cell mutation test and the sister chromatid exchange test; the maximum test concentration in both studies was 1%. In the unscheduled DNA synthesis assay, a statistically significant increase in radioactive thymidine incorporation into rat hepatocyte nuclei was noted only at the highest concentration tested (0.1%). PEG-150 was not mutagenic in the mouse lymphoma forward mutation assay when tested at concentrations up to 150 g/l (Andersen 1993).

CARCINOGENICITY

All of the carcinogenicity data available on the PEGs was specifically on PEG-8, which was used as a solvent control for a number of studies. PEG-8 was not carcinogenic when administered orally to mice (30 weeks of dosing), intraperitoneally to rats (6 months of dosing), subcutaneously (20 weeks of dosing to rats; 1 year of dosing to mice), or when injected into the gastric antrum of guinea pigs over a period of 6 months (Andersen 1993).

CLINICAL STUDIES

In clinical studies, PEG-6 and PEG-8 induced mild sensitization in 9% and 4% of 23 male subjects tested, respectively. However, later production lots of PEG-6, as well as PEG-75, did not cause reactions in any of the 100 male and 100 female subjects tested. A product formulation containing 3% PEG-8 induced minimal to mild irritation (induction phase) in over 75% of 90 volunteers participating in a skin irritation and sensitization study. Responses (not classified) were noted in 22 subjects at the 24-hour challenge reading. Cases of systemic toxicity and contact dermatitis in burn patents were attributed to PEG-based topical ointments. The ointment that induced systemic

toxicity contained 63% PEG-6, 5% PEG-20, and 32% PEG-75 (Andersen 1993).

Extensive clinical experience indicates that the incidence of sensitivity to lanolin and its derivatives was low in exposed persons. Photosensitization was not induced by these types of ingredients. Comedogenic effects from cosmetics incorporating lanolin and related materials have been reported (Elder 1980).

SUMMARY

PEGs Lanolin, PEGs Hydrogenated Lanolin, PEG Lanolin Oil, and PEG Lanolin Wax are the polyethylene glycol derivatives of lanolin, hydrogenated lanolin, lanolin oil, and lanolin wax. These ingredients function as surfactants and as hair- and skin-conditioning agents in cosmetics. Product formulation data submitted to the FDA indicate that these ingredients were used in a total of 238 product formulations.

Few data on the PEGs Lanolin were available regarding metabolism, toxicity, mutagenicity, carcinogenicity, and clinical safety. Therefore, this report presented data on the PEGs, Lanolin, and Lanolin Oil separately, with the view that these data were applicable to the PEGs Lanolin.

PEG Lanolin absorption and metabolism data were not available. PEG absorption is related to the molecular weight. Low molecular weight PEGs are readily absorbed through damaged skin. Oral and intravenous studies on PEGs indicate that these substances are excreted, unchanged, in the urine and feces.

In toxicity studies, the PEGs and Lanolin had low oral and dermal toxicities. PEGs were nonirritating to the skin of rabbits and guinea pigs, and PEG-75 was not a sensitizer. When used at 100% concentrations, Lanolin and its derivatives were nonirritating or mildly irritating.

Although ethylene glycol and its monoalkyl ethers are reproductive toxins and teratogenic agents, it was considered unlikely that the PEG Lanolin compounds would cause reproductive or teratogenic effects based on their structural characteristics. In subchronic and chronic feeding studies, PEG-6-32 and PEG-75 did not induce reproductive effects in rats.

In mutagenicity studies, PEG-8 was negative in the Chinese hamster ovary cell mutation test and the sister chromatid exchange test. At a concentration of 150 g/l, PEG-150 was not mutagenic in the mouse lymphoma forward mutation assay. PEG-8 was not carcinogenic when administered orally, intraperitoneally, or subcutaneously.

In clinical studies, PEG-8 was a mild sensitizer and irritant. Contact dermatitis and systemic toxicity in burn patients were attributed to a PEG-based topical ointment. Sensitivity to Lanolin and its derivatives was low. Comedogenic activity by cosmetics incorporating lanolin have been reported.

DISCUSSION

Safety test data on the original PEGs Lanolin reviewed by the CIR Expert Panel were considered relevant to this review. Likewise, the data on PEGs and on Lanolin and its derivatives were considered relevant. All these data were supportive of the safety of the additional PEGs Lanolin polymers, the PEGs Hydrogenated Lanolin polymers, PEG-75 Lanolin Oil, and PEG-75 Lanolin Wax.

The Panel concluded that based on the structure of each PEG Lanolin that was reviewed, none of these ingredients was likely to be mutagenic or carcinogenic. Additionally, based on particle size and cosmetic use concentrations, it is not likely that these ingredients, in formulation, are respirable. Thus, the Expert Panel has no concerns regarding the absence of inhalation toxicity data, and the Panel considers the PEGs Lanolin safe for use in aerosolized products.

The Panel noted that comedogenic effects have resulted from the use of cosmetic products containing lanolin compounds and that data on the comedogenicity of PEGs Lanolin are not available. However, it was concluded that the comedogenic potential of these compounds in cosmetics is of minor concern.

The Panel was concerned about the sensitization potential of PEGs Lanolin (PEG-5, -10, -20, -24, -25, -27, -30, -35, -40, -50, -55, -60, -75, -85, -100, and -150 Lanolin; PEG-5, -10, -20, -24, -30, and -70 Hydrogenated Lanolin; PEG-75 Lanolin Oil; and PEG-75 Lanolin Wax) when applied to damaged skin. This concern arose because of positive patch tests for PEG-6 and PEG-8 in burn patients treated with a dressing that contained PEG-6, PEG-20, and PEG-75. The general corollary is that as the molecular weight of a compound decreases, expected irritancy and sensitization are increased. Consequently, product formulations should be adjusted in order to minimize any untoward effects.

It was also noted that it is unlikely that the PEGs Lanolin are photoactivated ingredients, considering that product formulations containing Lanolin compounds did not induce photosensitization or phototoxicity when applied to human subjects.

As discussed in this report, the possibility of reproductive and developmental effects was determined not to be of concern.

CONCLUSION

The CIR Expert Panel concludes that PEG-5, -10, -24, -25, -35, -55, -100, and -150 Lanolin; PEG-5, -10, -20, -24, -30, and -70 Hydrogenated Lanolin; PEG-75 Lanolin Oil; and PEG-75 Lanolin Wax are safe for use in cosmetic formulations under the present practices of use.

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