

Final Report of the Safety Assessment for PEG-75 Lanolin, PEG-20 Lanolin, PEG-27 Lanolin, PEG-30 Lanolin, PEG-40 Lanolin, PEG-50 Lanolin, PEG-60 Lanolin, and PEG-85 Lanolin

PEG Lanolins are the polyethylene glycol ethers of whole lanolin. They are widely used in cosmetics as auxiliary oil/water emulsifiers at concentrations of up to 25%.

PEG Lanolins were found to be nontoxic in acute oral, dermal, and inhalation studies at varying concentrations. They caused little or no eye irritation in rabbits at concentrations of 50–100%. PEG Lanolins at 10–100% caused mild or negligible skin irritation and were reported to be nonsensitizing in guinea pigs. PEG Lanolins were reported to be nonirritating and nonsensitizing in patients at concentrations from 10–60%.

On the basis of the available information, it is concluded that the PEG-75 Lanolin Group is safe as presently used in cosmetic products.

CHEMISTRY

Structure

LANOLIN is the purified secretory product of sheep sebaceous glands. PEG Lanolins are the polyethylene glycol ethers of lanolin; they are prepared by ethoxylating the hydroxy fatty acids, hydroxy esters, sterols, and alcohols present in whole lanolin. Table 1 gives a typical composition of whole lanolin.⁽¹⁻³⁾

TABLE 1. COMPOSITION OF WHOLE LANOLIN.^a

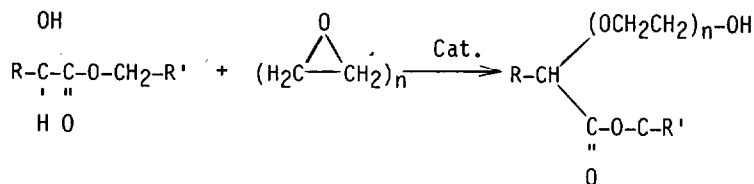
<i>Group</i>	<i>Percent of whole lanolin</i>
Esters of sterols and triterpene alcohols	35.4
Esters of aliphatic alcohols	23.7
Monohydroxy esters of sterols and of triterpene and aliphatic alcohols	20.0
Di- and polyhydroxyesters and free diols	7.9
Free aliphatic alcohols	5.6
Free sterols	4.1
Free hydrocarbons	0.6
Free fatty acids	0.5
Unknowns	2.2
Total	100.0

^aFrom Ref. 1.

COSMETIC INGREDIENT REVIEW

Two related groups of cosmetic ingredients, the Acetylated Lanolin Alcohols and the Ethoxylated Lanolin Alcohols (Laneths), have already been reviewed by CIR and determined by the Expert Panel to be safe at the concentrations presently used in cosmetic formulations.^(1,2)

PEG Lanolins are prepared by the reaction of an average of n moles ethylene oxide ($n = 20, 27, 30, 40, 50, 60, 75$, or 85) 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 below.^(4,5)



where n = number of moles ethylene oxide, R = lanolin hydroxyacids, and R' = lanolin alcohols.

Upon completion of the reaction, the catalyst is acid-neutralized and the product vacuum stripped to remove any unreacted ethylene oxide. The insoluble salts formed from neutralization of the catalyst are then filtered from the PEG Lanolin. Following this step, the product may be further filtered and/or refined.^(4,5)

Properties

All PEG Lanolins are partially soluble in water and/or alcohol and may be completely or partially 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 five percent aqueous solution of PEG-30 Lanolin has been reported to have a pH of 4–7.^(4,5)

Table 2 lists other properties of PEG Lanolins.⁽⁵⁾

Analytical Methods

Spilker and Richey⁽⁶⁾ have described a number of analytic techniques useful for Lanolin and Lanolin derivatives. These generally include hydrolysis, fractionation, separation by chromatography, and identification. Infrared (IR) spectroscopy is also used to identify PEG Lanolins.⁽⁵⁾

Impurities

According to the *CTFA Cosmetic Ingredient Chemical Description*, the only impurities found in PEG-75 Lanolin are inorganic salts (0.25% max.). No impurities were listed for the other PEG Lanolins.⁽⁵⁾

Trace amounts of 1,4-dioxane, a reaction product of the ethoxylation process, may be present in PEG Lanolins. Analytical data were not available. Pesticides and trace metals found in crude lanolin may also be present.⁽¹¹⁾

USE

PEG Lanolins are used in cosmetics as emollients, lubricants, and auxiliary oil/water emulsifiers. Added to detergents, they minimize defatting action on skin and hair while not affecting the cleansing action. PEG Lanolins impart the same properties to cosmetics as lanolin does, but because of their higher solubility in water and alcohol, they can be included in a greater variety of formulations.⁽⁴⁾

TABLE 2. PROPERTIES OF VARIOUS PEG LANOLINS.^a

<i>Ingredient</i>	<i>Solvents</i>	<i>Additives</i>	<i>Saponification</i>	<i>Iodine value</i>	<i>Hydroxyl value</i>	<i>Acid value (max)</i>	<i>Water content (percent)</i>
PEG-20 Lanolin	None	Water (3% max)	20-36	— ^b	20-46	3.0	3.0 (max)
PEG-27 Lanolin	Water	None	12-24	12 max	—	—	51 (max)
PEG-30 Lanolin	None	None	19-35	—	—	4.0	3 (max)
PEG-40 Lanolin	Water	None	18-36	—	25-45	4.0	—
PEG-50 Lanolin	None	Water (3% max)	8-18	—	10-25	2.0	3 (max)
PEG-60 Lanolin	Water	None	8-16	10 max	—	2.0	—
PEG-75 Lanolin	Water	BHT (0.05%)	10-24	—	25-75	4.0	—
PEG-85 Lanolin	Water	None	16 max	8 max	—	—	51 (max)

^aFrom Ref. 5.^b—Data not available.

COSMETIC INGREDIENT REVIEW

PEG Lanolins are generally used in concentrations of 0.1–5%; one moisturizing formulation was reported to contain 10–25% PEG-75 Lanolin. Table 3 outlines product formulation data for PEG Lanolins.⁽⁴⁹⁾

BIOLOGICAL PROPERTIES

Animal Toxicology

Acute Toxicity

Oral

Various PEG Lanolins were tested for acute oral toxicity; they were reported to be relatively non-toxic in concentrations at or greater than the maximum level used in cosmetics. The results are summarized in Table 4.

Dermal

The acute dermal toxicity of PEG-27 and PEG-75 Lanolins was reported in two separate studies on six and 16 rabbits, respectively. In each study, skin sites were abraded in half of the test animals. The PEG Lanolins were then applied under occlusion with rubber sleeves and the animals immobilized for 24 h. After the sleeves were removed, the skin was observed for two weeks. In the first test, at a dose of 2.0 ml/kg, undiluted PEG-27 Lanolin caused no erythema, edema, or toxic symptoms in any of the six rabbits, and the acute dermal LD50 was reported to be >2.0 ml/kg.⁽⁷⁾

Undiluted PEG-75 Lanolin was tested on four groups of four rabbits at doses of 1.00, 2.15, 4.64, and 10.0 ml/kg. One animal at dose 10.0 ml/kg died on Day 14 of observation. Mild transient edema (at 10 ml/kg only), mild diffuse erythema, mild desquamation, and ataxia, all of various durations, were observed in a number of test animals; however, no dose-effect relationship was reported. Gross necropsy of surviving animals revealed no abnormalities. The acute dermal LD50 of undiluted PEG-75 Lanolin was determined to be >10 ml/kg.⁽¹⁷⁾

Inhalation

Ten albino rats were exposed for one hour to an aerosol containing PEG-27 Lanolin (200 mg/l) in a test which used the Federal Hazardous Substance Labeling Act (FHSLA) procedures. The animals were observed for two weeks; none exhibited toxic reactions to PEG-27 Lanolin. Autopsies conducted upon the completion of the observation period revealed no abnormalities.⁽¹⁸⁾

Subchronic Toxicity

Dermal

PEG-75 Lanolin was tested for subchronic dermal toxicity in five groups of four rabbits each. The back and flanks of each rabbit was clipped free of hair and the skin was abraded in two animals in each group. Three of the five groups received inunctions of 2 ml/kg of 5%, 15%, or 50% PEG-75 Lanolin in mineral oil. The remaining two groups received 2 ml/kg mineral oil. The materials were applied daily five days per week for three weeks. The rabbits were immobilized throughout the test and were observed for changes in weight, hemoglobin, and hematocrit and total and differential leucocyte counts. Animals sacrificed and autopsied after five weeks showed no visible skin irritation or abnormalities attributable to the application of PEG-75 Lanolin.⁽¹⁹⁾

Acute Irritation

Eye

PEG Lanolins were tested with the Draize or Modified Draize procedure for potential irritancy to eyes of rabbits. In over half of the tests, eyes were washed after introduction of the test substance. Eye irritation was observed and scored for a number of days after instillation of the ingredient. Table 5 outlines the results of these tests. In cases where irritation was observed, only the conjunctiva was affected. The highest mean irritation score at any observation was 3.33 (maximum score = 110) indicating mild irritation. All irritation subsided by the fourth day with the exception of one case (PEG-75 Lanolin) in which the conjunctiva remained irritated throughout the test period. These results indicate that PEG Lanolins at concentrations of 50–100% are, at worst, mild eye irritants.

ASSESSMENT: PEG LANOLINS

TABLE 3. Product Formulation Data.^a

<i>Ingredient/Cosmetic product type</i>	<i>Concentration (percent)</i>	<i>No. of product formulations</i>
PEG-20 Lanolin		
Eyeliners	> 1-5	15
Eye shadows	> 5-10	10
	> 1-5	6
	> 0.1-1	3
Face, body, and hand preparations	> 0.1-1	1
Moisturizing	> 1-5	1
	> 0.1-1	1
Other skin care preparations	> 1-5	2
	> 0.1-1	1
PEG-27 Lanolin		
Hair conditioners	> 0.1-1	1
Permanent waves	> 0.1-1	4
Shampoos	> 0.1-1	5
Shaving creams	> 1-5	2
	> 0.1-1	7
PEG-30 Lanolin		
Hair conditioners	> 0.1-1	5
PEG-40 Lanolin		
Eyeliners	> 1-5	2
Permanent waves	> 0.1-1	4
Wave sets	> 0.1-1	1
Face, body, and hand preparations	> 1-5	1
	> 0.1-1	3
PEG-50 Lanolin		
Other bath preparations	> 1-5	1
Hair straighteners	> 1-5	7
Permanent waves	> 1-5	2
Shampoos	> 1-5	2
	≤ 0.1	2
Cleansing	≤ 0.1	1
Face, body, and hand preparations	> 0.1-1	1
Skin fresheners	> 1-5	1
Other skin care preparations	> 1-5	1
	> 0.1-1	1
Suntan gels, creams, and liquids	> 0.1-1	1
PEG-60 Lanolin		
Bath oils	> 5-10	1
Permanent waves	> 1-5	1
Shampoos	> 1-5	1
Cleansing	> 1-5	1
PEG-70 Lanolin		
Bubble baths	> 0.1-1	1
PEG-75 Lanolin		
Baby shampoos	> 0.1-1	3
Bath oils	> 0.1-1	4
	≤ 0.1	1
Bubble bath	> 0.1-1	4
Other bath preparations	> 1-5	2
Eyeliners	> 0.1-1	1
Hair conditioners	> 1-5	5
Hair sprays	> 0.1-1	2
	≤ 0.1	14

COSMETIC INGREDIENT REVIEW

TABLE 3. (Continued).

<i>Ingredient/Cosmetic product type</i>	<i>Concentration (percent)</i>	<i>No. of product formulations</i>
Hair straighteners	> 5-10	3
	> 1-5	4
	> 0.1-1	1
Permanent waves	> 5-10	1
	> 1-5	13
	> 0.1-1	5
Rinses	> 0.1-1	4
Shampoos	> 1-5	9
	> 0.1-1	18
Tonics and dressings	> 0.1-1	2
	≤ 0.1	1
Wave sets	> 0.1-1	4
Other hair preparations	> 0.1-1	2
Hair bleaches	> 1-5	1
Coloring shampoos	> 0.1-1	1
Face powders	> 0.1-1	1
Nail polish remover	> 1-5	1
	> 0.1-1	1
Bath soaps and detergents	> 1-5	2
Other personal cleanliness products	> 0.1-1	1
	≤ 0.1	1
Aftershave lotions	> 0.1-1	1
Suntan gels, creams, and liquids	> 0.1-1	1
Cleansing	> 5-10	1
	> 1-5	8
	> 0.1-1	1
Face, body, and hand preparations	> 0.1-1	7
Skin fresheners	> 1-5	3
	≤ 0.1	1
Hormone	> 5-10	1
Moisturizing	> 10-25	1
	> 1-5	4
	> 0.1-1	4
<i>PEG-85 Lanolin</i>		
Other bath preparations	> 1-5	2
	> 0.1-1	4
Eyeliners	> 5-10	1
Hair sprays	≤ 0.1	3
Rinses	> 0.1-1	1
Shampoos	> 1-5	1
Tonics, dressings, and other grooming preparations	> 1-5	1
Wave sets	> 1-5	3
	> 0.1-1	12
Makeup bases	> 0.1-1	1
	≤ 0.1	2
Nail polish removers	≤ 0.1	1
Cleansing	> 0.1-1	1
Face, body, and hand preparations	> 0.1-1	1

^aFrom Ref. 49.

TABLE 4. ACUTE ORAL TOXICITY OF VARIOUS PEG LANOLINS.

<i>Lanolin</i>	<i>Conc. (percent)</i>	<i>Dosage</i>	<i>Route</i>	<i>Animal (M/F)</i>	<i>No. animals per dose/total</i>	<i>Acute oral LD50</i>	<i>Comments</i>	<i>Ref.</i>
PEG-20	30	15.9 g/kg	G.I. ^a	Rat (10/10)	20/20	> 15.9 g/kg	One death—no data.	8
PEG-27	100	5.0 ml/kg	G.I.	Rat (5/5)	10/10	> 5.0 cc/kg	—	7
PEG-40	100	2.0–32 g/kg	G.I.	Rat (20/20)	5/40	18.5 g/kg	Lethargy with impaired locomotion, diarrhea, unkempt coats at doses 16 and 20 g/kg. Coma preceded death at 25 and 32 g/kg.	10
PEG-40	50	2.0–32 g/kg	G.I.	Rat	5/35	20.6 g/kg	—	10
PEG-50	30	15.9 g/kg	G.I.	Rat (0/10)	10/10	> 15.9 g/kg	—	9
PEG-75	100	2.5–40 g/kg	G.I.	Rat	2/10	~ 30 g/kg	—	13
PEG-75	100	0.7–21.3 g/kg	G.I.	Rat (15/15)	5/30	> 21.3 g/kg	Diarrhea and unkempt coats at doses 10.7 and 21.3 g/kg.	12
PEG-75	100	50 and 100 ml/kg	G.I.	Mouse	5, 10/15	> 100 cc/kg	—	14
PEG-75	50	8–64 ml/kg	G.I.	Rat (15/15)	5/30	54 cc/kg	Where death occurred, debility was slow. Dead animals with nasal hemorrhage and oozing urine.	12
PEG-75	50	0.46–10 ml/kg	G.I.	Rat (25/0)	5/25	> 10 cc/kg	—	15
PEG-75	50	20 ml/kg	G.I.	Rat (10/0)	10/10	> 20 cc/kg	Congested renal tubules in 11 test animals.	13
PEG-75	25	0–16 g/kg	G.I.	Rat (15/15)	10/30	> 16 g/kg	Pilo-erection, lethargy, diarrhea, and matted fur in test animals.	16
PEG-85	100	1.0–32 g/kg	G.I.	Rat (15/15)	5/30	> 32 g/kg	—	11

^aGastric intubation.

TABLE 5. PRIMARY EYE IRRITATION OF VARIOUS PEG LANOLINS.

<i>Lanolin</i>	<i>Conc. (percent)</i>	<i>Method</i>	<i>No. of rabbits</i>	<i>No. eyes washed/time</i>	<i>Mean scores hour/day</i>								<i>Comments</i>	<i>Ref.</i>
					<i>1 h</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>	<i>6</i>	<i>7</i>		
PEG-20	100	Draize	9	3/2 sec	0	0	0	0	0	—	—	0	Nonirritating.	20
PEG-27	100	FHSLA	6	0	—	0	0	0	—	—	—	—	Nonirritating.	21
PEG-30	100	FDA ^a	5	5/5 min	2.0	0.8	0	0	0	—	—	0	Conjunctival irritation.	22
PEG-30	100	FDA	3	3/24 h	2.0	2.0	1.3	1.3	0	—	—	0	Conjunctival irritation.	22
PEG-40	100	Draize	9	3/2 sec	0	0	0	0	0	0	0	0	Nonirritating.	23
PEG-40	50	Draize	9	3/4 sec 3/2 sec 3/4 sec	0	0	0	0	0	0	0	0	Nonirritating.	23
PEG-50	50	Draize	6	0	2.0	0	0	0	0	—	—	0	Conjunctival irritation.	24
PEG-50	50	Draize	3	3/2 sec	0.67	0	0	0	0	—	—	0	Conjunctival irritation.	24
PEG-75	100	FHSLA	6	0	—	3.33	2.00	2.00	—	—	—	0.33	Conjunctival irritation.	25
PEG-75	100	FDA	6	0	—	0	0	0	—	—	—	—	Nonirritating.	26
PEG-75	100	Draize	9	3/2 sec 3/4 sec	0	0	0	0	0	0	0	0	Nonirritating.	27
PEG-75	100	Draize	6	0	—	0	0	0	—	—	—	—	Nonirritating.	28
PEG-75	50	Draize	9	3/2 sec 3/4 sec	0	0	0	0	0	0	0	0	Nonirritating.	27
PEG-75	50	Draize	9	3/2 sec 3/4 sec	0	0	0	0	0	—	—	0	Nonirritating.	29
PEG-85	50	FDA	6	0	3.33	3.33	2.67	1.33	0	0	0	0	Conjunctival irritation.	30

^aFDA = Federal Register 37 No. 83 Section 191.12.

ASSESSMENT: PEG LANOLINS

Skin

The Draize method or a modification of it was used to evaluate the potential skin irritancy of various PEG Lanolins. Results of these tests are summarized in Table 6. Most of the PEG Lanolins caused mild or negligible irritation, even at 100% concentrations. However, PEG-30 Lanolin at 100% was a moderate irritant; it had a Primary Irritation Index (PII) of 2.3 (maximum = 8). During the 72-hour observation period, the animals tested with PEG-30 Lanolin experienced some edema and erythema.

The "corrosiveness" of undiluted PEG-75 Lanolin was tested on six rabbits. The undiluted ingredient (0.5 ml) was applied to intact skin under occlusive patches (according to FHSLA procedures); no erythema, edema, or tissue destruction resulted. It was concluded that undiluted PEG-75 Lanolin was noncorrosive.⁽⁴¹⁾

Department of Transportation (DOT) procedures were used to test PEG-75 and PEG-40 Lanolins for dermal corrosiveness on intact and abraded skin of rabbits. Both PEG-40 Lanolin at 50% and 100% concentrations and PEG-75 Lanolin at 100% were reported to be noncorrosive to intact and abraded skin.^(42,43)

Sensitization

PEG-75 Lanolin was tested for skin sensitization on 10 male albino guinea pigs. A 0.1% aqueous dispersion of PEG-75 Lanolin was injected intradermally every other day for a total of 10 injections. A challenge injection was given three weeks after the last sensitizing injection. The area and intensity of reactions were measured 24 h after every injection. There were no significant differences between induction and challenge scores. This ingredient was considered to be nonsensitizing under test conditions.⁽⁴⁴⁾

TABLE 6. PRIMARY SKIN IRRITATION OF VARIOUS PEG LANOLINS.

<i>Lanolin</i>	<i>Conc. (percent)</i>	<i>Method</i>	<i>No. of rabbits</i>	<i>PII</i>	<i>Comment</i>	<i>Ref.</i>
PEG-20	100	FHSLA	6	0	Nonirritating.	31
PEG-27	100	FHSLA	6	0	Nonirritating.	32
PEG-30	100	FDA ^a	6	2.3	Very slight to well defined erythema with or without slight edema on all animals during 72-hour observation.	33
PEG-40	100	Draize	6	0	Nonirritating.	34
PEG-40	100	DOT	6	0	Nonirritating.	34
PEG-40	50	Draize	6	0	Nonirritating.	34
PEG-40	50	DOT	6	0	Nonirritating.	34
PEG-50	60	FHSLA	6	0	Nonirritating.	50
PEG-75	100	FHSLA	6	0.30	Slight erythema on intact and abraded sites at 24 and 72 h.	35
PEG-75	100	Draize	6	0	Nonirritating.	12
PEG-75	100	DOT	6	0	Nonirritating.	12
PEG-75	100	FHSLA	6	0.42	Slight erythema at 24 h on 2 intact and 4 abraded sites. Slight erythema at 72 h each site of 2 rabbits.	36
PEG-75	100	Draize	3	0	Nonirritating.	37
PEG-75	50	Draize	6	0.80	Slight erythema on all sites during 72-hour observation period.	12
PEG-75	50	Draize	6	0	Nonirritating.	38
PEG-75	10	FHSLA	6	0.08	Slight erythema (1+) on intact and abraded sites at 24 and 72 hours.	39
PEG-85	100	FHSLA	6	0.13	Slight erythema on abraded sites at 24 and 72 h.	40

^aFDA = Federal Register, 17 September, 1964 Section 191.12.

COSMETIC INGREDIENT REVIEW

Other

Data were not available on absorption, metabolism, excretion, teratogenesis, mutagenesis, carcinogenicity, or photosensitivity.

Clinical Assessment

PEG-75 Lanolin was tested at concentrations of 20%, 40%, 60%, 80%, and 100% on five groups of subjects totaling 53. Under an occlusive patch, 0.01 ml/cm² of the ingredient was applied to the skin and left in place for 24 h. The patch was then removed, the site scored, and a fresh patch reapplied to the same site; this test procedure was repeated four consecutive days per week for three weeks. After no reactions were elicited by any of the first four induction patches, the concentration of PEG-75 Lanolin was raised to 100% for all subjects for the remainder of the experiment. Seventeen days after removal of the last patch, a challenge patch was applied to a virgin site and left in place for 24 h. Challenge sites were scored at 24, 48, and 72 h. Neither induction nor challenge patches caused irritation. PEG-75 Lanolin was considered to be nonirritating and nonsensitizing.⁽⁴⁵⁾

In three separate studies, PEG-20 and PEG-50 Lanolins, at 10–60% concentrations, were tested for irritation and sensitization. Test material was applied under occlusive patches and left in place for either 48 or 72 h; the patches were then removed and the site scored. After rest periods of 7–14 days, a 72-hour challenge patch was applied and the sites scored after the patches were removed. PEG-20 Lanolin was tested at 30% and 10% concentrations on 50 and 10 subjects, respectively. No irritation occurred in subjects as a result of induction or challenge patches. The ingredient was therefore considered to be nonirritating and nonsensitizing under test conditions and at test concentrations.⁽⁴⁶⁾ When 60% PEG-50 Lanolin was tested on 201 subjects, no irritation resulted from induction or challenge patches. This ingredient was considered to be nonirritating and nonsensitizing under test conditions.⁽⁴⁷⁾

Although it would be desirable to have phototoxicity and photosensitivity data, common clinical experience does not indicate that either is caused by PEG Lanolin compounds.

A chemical manufacturing company which has been producing PEG-40 Lanolin and PEG-75 Lanolin for about 20 years reports no complaints of adverse effects from workers who handle these ingredients.⁽⁴⁸⁾

SUMMARY

PEG Lanolins are the polyethylene glycol ethers of whole lanolin. They are prepared by reacting *n* moles of ethylene oxide with each mole of lanolin. PEG Lanolins are widely used in cosmetics as auxiliary oil/water emulsifiers. They are typically used at concentrations of 0.1–5%; one moisturizer contains PEG-75 Lanolin at 10–25%.

PEG Lanolins were found to be nontoxic in acute oral, dermal, and inhalation studies at varying concentrations. PEG-75 Lanolin was reported to be nontoxic in a subchronic dermal study at concentrations of 5%, 15%, and 50%. PEG Lanolins caused little or no eye irritation in rabbits at concentrations of 50–100%. PEG Lanolins at 10–100% caused mild or negligible skin irritation; in one study, however, PEG-30 Lanolin (100%) resulted in a PII of 2.3. PEG-75 Lanolin was reported to be nonsensitizing in guinea pigs.

PEG-75 Lanolin at 100% concentration caused no irritation or sensitization in 53 human subjects in a repeated insult patch test. A larger number of patients would have given the Expert Panel more confidence in the data. PEG-20 and PEG-50 Lanolins were also reported to be nonirritating and nonsensitizing in 261 patients at concentrations from 10 to 60 percent in prophetic patch tests.

CONCLUSION

On the basis of the available information, the Panel concludes that the PEG-75 Lanolin Group is safe as presently used in cosmetic products.

ASSESSMENT: PEG LANOLINS

ACKNOWLEDGMENT

Mr. Kevin Fisher, Scientific Analyst and writer prepared the technical analysis used by the Expert Panel in developing this report.

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13. FOOD and DRUG RESEARCH LABORATORIES (FDRL). (December, 1974). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-75 Lanolin. Appendix 1. Acute Oral Toxicity.*
14. LEBERCO LABORATORIES. (September, 1973). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-75 Lanolin. Appendix 2. Acute Oral Toxicity.*
15. HILLTOP RESEARCH. (June, 1971). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-75 Lanolin. Appendix 5. Acute Oral Toxicity.*
16. WESTBROOK LANOLIN LABORATORIES. (May, 1973). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-75 Lanolin. Supplement. Acute Oral Toxicity.*
17. HILLTOP RESEARCH. (June, 1971). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-75 Lanolin. Appendix 5. Acute Dermal Toxicity.*
18. BTL. (July, 1975). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-27 Lanolin. Appendix 5. Acute Dermal Toxicity and Inhalation.*
19. ROSNER-HIXSON LABORATORIES. (February, 1965). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-75 Lanolin. Appendix 4. Subchronic Dermal Toxicity.*
20. ICI AMERICA. (April, 1976). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-20 Lanolin. Appendix 6. Eye Irritation.*
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22. HUNTINGDON RESEARCH CENTER. (February, 1973). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-30 Lanolin. Supplement. Eye Irritation.*

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23. BTL. (October, 1975). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-40 Lanolin. Appendix 3. Eye Irritation.*
24. ICI AMERICA. (January, 1976). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-50 Lanolin. Appendix 6. Eye Irritation.*
25. FDRL. (December, 1974). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-75 Lanolin. Appendix 1. Eye Irritation.*
26. LEBERCO LABORATORIES. (September, 1973). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-75 Lanolin. Appendix 2. Eye Irritation.*
27. BTL. (June, 1970). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-75 Lanolin. Appendix 3. Eye Irritation.*
28. HILLTOP RESEARCH. (June, 1971). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-75 Lanolin. Appendix 5. Eye Irritation.*
29. ROSNER-HIXSON LABORATORIES. (February, 1965). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-75 Lanolin. Appendix 4. Eye Irritation.*
30. BTL. (November, 1976). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-85 Lanolin. Appendix 5. Eye Irritation.*
31. ICI AMERICA. (April, 1976). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-20 Lanolin. Appendix 6. Primary Skin Irritation.*
32. BTL. (July, 1975). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-27 Lanolin. Appendix 5. Primary Skin Irritation.*
33. HUNTINGDON RESEARCH CENTER. (February, 1973). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-30 Lanolin. Supplement. Primary Skin Irritation.*
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36. HILLTOP RESEARCH. (June, 1971). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-75 Lanolin. Appendix 5. Primary Skin Irritation.*
37. LEBERCO LABORATORIES. (September, 1973). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-75 Lanolin. Appendix 2. Primary Skin Irritation.*
38. ROSNER-HIXSON LABORATORIES. (February, 1965). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-75 Lanolin. Appendix 4. Skin Irritation.*
39. CONSUMER PRODUCT TESTING. (November, 1976). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-75 Lanolin. Appendix 1. Primary Skin Irritation.*
40. BTL. (November, 1976). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-85 Lanolin. Appendix 5. Primary Skin Irritation.*
41. FDRL. (December, 1974). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-75 Lanolin. Appendix 1. Dermal Corrosion.*
42. CONSUMER PRODUCT TESTING. (November, 1976). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-40 Lanolin. Appendix 1. Dermal Corrosion.*
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44. ROSNER-HIXSON LABORATORIES. (February, 1965). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-75 Lanolin. Appendix 4. Sensitivity.*
45. PRODUCT INVESTIGATIONS. (April, 1977). Submission of data in support of safety of PEG-Lanolins. Prepared by CTFA Sub-Task Force. PEG-75 Lanolin. Appendix 1. Clinical Assessment.*
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49. FOOD AND DRUG ADMINISTRATION (FDA). (August 31, 1976). Cosmetic product formulation data. Ingredients Used in Each Product Category. Washington, DC: Food and Drug Administration.
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