FINAL REPORT OF THE SAFETY ASSESSMENT FOR ISOPROPYL LANOLATE

Isopropyl Lanolate is used in many types of cosmetic products which contact the skin, mucous membranes, and respiratory tract daily and over long periods of time.

Isopropyl Lanolate had an acute oral LD50 >40g/kg in the rat; a very mild, transient primary irritant effect on the skin of the rabbit and guinea pig; and a slight promptly reversible, irritant action on the conjunctivae of the rabbit. Skin sensitization and photosensitization tests were negative in the white guinea pig.

Skin irritation studies in humans were negative, with the exception of one study in which six out of 53 subjects showed some irritation at high concentrations. Two of 53 subjects classed as hyper-reactive by the investigator indicated sensitivity at high concentrations of Isopropyl Lanolate. Human patch tests with cosmetic formulations containing 6 and 14 percent Isopropyl Lanolate were "very slightly irritating." None of the three formulations tests produced contact allergy sensitization.

On the basis of the information available, it is concluded that Isopropyl Lanolate is safe as currently used in cosmetic products.

CHEMICAL AND PHYSICAL PROPERTIES

Structure and Properties

Isopropyl Lanolate is a mixture of isopropyl esters of lanolin acids. The lanolin acids are derived from natural lanolin by hydrolysis. After purification the acids are esterified with isopropanol using a suitable catalyst system. Lanolin fatty acids are a mixture of normal and branched chain and hydroxy acids, ranging in length from C_{12} to C_{34}. Therefore, Isopropyl Lanolate is a mixture of isopropyl esters of these acids. Their average composition is given in Table 1.

The following properties characterize Isopropyl Lanolate (CTFA, 1978a):

Property	Range
Melting point	26°C - 39°C
Specific gravity 25°/25°	0.850 - 0.865
Acid value	20 maximum
Saponification value	135 - 165
Iodine value	6 - 20
Hydroxyl value	35 - 65
Moisture	0.2% maximum
Ash	0.2% maximum

TABLE 1. Typical Fatty Acid Composition of Lanolin

Group	Subgroup	Percentage	Carbon Chain Length Range	Predominant Constituents of Subgroup
Non-hydroxylated	nor	12.69	8-38	C_{24} (18.7%)[1], C_{16} (18), C_{26} (15.5)
	iso	22.08	8-38	C_{20} (1.7), C_{16} (16.5), C_{26} (14.6)
	anteiso	26.23	7-41	C_{25} (14.7), C_{19} (13.5), C_{27} (13.4)
	unsat.	2.10	-	mostly C_{16} and C_{18}
Alpha-hydroxylated	nor	21.71	10-32	C_{16} (88.3)
	iso	4.48	12-34	C_{18} (71.9)
	anteiso	0.81	11-33	C_{23} (40.9), C_{25} (19.8)
Omega-hydroxylated	nor	3.05	22-36	C_{30} (45), C_{32} (21.8), C_{28} (16.1)
	iso	0.81	22-36	C_{30} (39.6), C_{32} (32.6)
	anteiso	1.34	23-35	C_{31} (36), C_{25}(26.9), C_{33} (16.3)
Poly-hydroxylated	all	4.70	-	not characterized
TOTAL		100.00%		

[1]Percent of all within specified subgroup.

Analytical Methods

Spilker and Richey (1973) have described a number of methods for the analysis of lanolin derivatives involving hydrolysis, fractionation, chromatographic separation and identification.

USE

Purpose and Extent of Use in Cosmetics

Isopropyl Lanolate is one of the more versatile of the lanolin derivatives because of its surfactant properties and pigment dispersing ability. It is used in combination with mineral oil and isopropyl palmitate for pigments such as titanium dioxide, oxy red and red #9. In lipsticks, creams, lotions and aerosol emulsions, it acts as a lubricant and gives a high gloss (Conrad, 1962; Conrad *et al.*, 1965; Synyer, 1975; Murphy and Lieberman, 1976).

Isopropyl Lanolate has been used in cosmetics and topical pharmaceuticals for over 20 years. Its current use in cosmetic formulations reported to FDA is shown in Table 2 (FDA, 1976). About 5 percent of these formulations contain this ingredient at 10 to 25% by weight.

BIOLOGICAL PROPERTIES

Animal Toxicology

General Studies

Acute

Oral The acute oral LD50 of Isopropyl Lanolate is greater than 40 g/kg in the rat. Single-dose oral toxicity tests of this ingredient, undiluted or in various

TABLE 2. Prduct Formulation Data (FDA, 1976)

Ingredient	Cosmetic Product Type	Concentration (%)	Number of Product Formulations
Isopropyl Lanolate	Bath oils, tablets, and salts	> 0.1 to 1	3
	Other bath preparations	> 1 to 5	1
		> 0.1 to 1	1
	Eyeliner	> 10 to 25	1
		> 5 to 10	1
		> 1 to 5	61
		> 0.1 to 1	6
	Eye shadow	> 10 to 25	7
		> 5 to 10	62
		> 1 to 5	57
		> 0.1 to 1	58
	Eye makeup remover	> 1 to 5	1
	Mascara	> 5 to 10	1
		> 1 to 5	4
	Other eye makeup preparations	> 10 to 25	4
		> 1 to 5	7
	Eyebrow pencil	> 1 to 5	10
	Sachets	> 1 to 5	3
	Other fragrance preparations	> 0.1 to 1	4
	Hair conditioners	> 0.1 to 1	4
	Hair sprays (aerosol fixatives)	≤ 0.1	2
	Tonics, dressings, and other hair grooming aids	> 1 to 5	2
	Other hair preparations	> 1 to 5	1
	Blushers (all types)	> 10 to 25	1
		> 5 to 10	16
		> 1 to 5	32
		> 0.1 to 1	27
		≤ 0.1	8
	Face powders	> 1 to 5	16
		> 0.1 to 1	31
	Foundations	> 10 to 25	7
		> 5 to 10	19
		> 1 to 5	45
		> 0.1 to 1	17
	Lipstick	> 25 to 50	1
		> 10 to 25	30
		> 5 to 10	231
		> 1 to 5	64
		> 0.1 to 5	21
		≤ 0.1	1
	Makeup bases	> 10 to 25	3
		> 5 to 10	15
		> 1 to 5	43
		> 0.1 to 1	104
		≤ 0.1	11

TABLE 2. Continued

Ingredient	Cosmetic Product Type	Concentration (%)	Number of Product Formulations
Isopropyl Lanolate	Rouges	> 10 to 25	3
		> 1 to 5	5
		> 0.1 to 1	3
	Makeup fixatives	> 0.1 to 1	2
	Other makeup preparations	> 10 to 25	3
		> 5 to 10	3
		> 1 to 5	3
		> 0.1 to 1	10
	Deodorants (underarm)	> 1 to 5	1
		≤ 0.1	1
	Aftershave lotions	> 1 to 5	3
	Beard softeners	> 0.1 to 1	1
	Preshave lotions (all types)	> 0.1 to 1	4
		≤ 0.1	1
	Shaving creams (aerosol, brushless, and lather)	> 0.1 to 1	2
	Other shaving preparation products	> 1 to 5	1
	Cleansing (cold creams, cleansing lotions, liquids and pads)	> 5 to 10	1
		> 1 to 5	1
		> 0.1 to 1	3
	Face, body, and hand (excluding shaving preparations)	> 10 to 25	1
		> 1 to 5	20
		> 0.1 to 1	27
	Hormone	> 0.1 to 1	1
	Moisturizing	> 5 to 10	2
		> 1 to 5	24
		> 0.1 to 1	11
		≤ 0.1	4
	Night	> 5 to 10	1
		> 1 to 5	3
	Skin lighteners	> 1 to 5	1
	Skin fresheners	> 1 to 5	1
		> 0.1 to 1	1
	Wrinkle smoothing (removers)	> 5 to 10	2
	Other skin care preparations	> 1 to 5	4
	Suntan gels, creams, and lotions	> 5 to 10	1
		≤ 0.1	2
	Other suntan preparations	> 1 to 5	1
		> 0.1 to 1	1

vehicles, have been carried out on young adult white rats. The designs and results of these studies are summarized in Table 3. The administration in all cases was by intragastric intubation. No deaths occurred in two tests in which as much as 42.7 g/kg of Isopropyl Lanolate was administered.

TABLE 3. Acute Oral Toxicity

Test Material	Species	Dose/kg	Mortality (%)	LD50/kg	References
Distilled Isopropyl Lanolate	Rat (5M & F)	2 ml	0		CTFA, 1977
		4 ml	0		
		8 ml	0	>64 ml	
		16 ml	0		
		32 ml	0		
		64 ml	0		
Isopropyl Lanolate	Rat (5M & F)	as above	0	>64 ml >42.7 g	Bio-Tox. Labs., 1970
Isopropyl Lanolate (50% solution in vegetable oil)	Rat (1M, 1F)	2.5 g	0		
		5.0 g	0		
		10.0 g	0	>40 g	Bio-Tox. Labs., 1974
		20.0 g	0		
		40.0 g	0		
Isopropyl Lanolate (100%)	Rat (1M, 1F)	as above	0	>40 ml	Food and Drug Res. Labs., 1974
Isopropyl Lanolate (40% suspension in arachis oil)	Rat (5M, 5F)	0	0	>16 g	Food and Drug Res. Labs., 1973
		10 g	0		
		16 g	10 (1F)		
Isopropyl Lanolate (2%)[1]	Rat (5M, 5F)	92.9 g (of mixture)	0	...	CTFA, 1978
Isopropyl Lanolate (6% in makeup concealer)	Rat	...	...	>15.9 g	CTFA, 1978

[1]Two percent Isopropyl Lanolate "in a soft, non-pourable cream with a low pH in a non-ionic oil-in-water emulsion."

Skin Irritation Table 4 shows the results of ten tests on six different preparations of Isopropyl Lanolate. These tests were all performed by standardized procedures involving the application of 0.5 ml of the test material to each of two areas (one abraded and the other intact) on the clipped back of each experimental animal. The test animal was the rabbit in all cases except one in which the guinea pig was used. The Primary Irritation Index (PII) score did not exceed 2.0 in any test out of a maximum possible score of 8. The scores ranged from 0.2 to 1.9 in seven tests, and were zero in the other three. It was concluded that Isopropyl Lanolate has a mild irritant action in tests for primary skin irritancy in the rabbit and guinea pig (Bio-Tox. Labs., 1970).

Eye Irritation The designs and results of eight rabbit eye irritation tests of various preparations of Isopropyl Lanolate, and of three tests on products containing 2, 6, and 20% Isopropyl Lanolate, respectively, are summarized in Table 5. It is noted that the application of the undiluted ingredient resulted in mean scores ranging from 0 to 7.7 out of a maximum possible score of 110, reflecting no irritation to "slight," "mild," "minimal," or "marginal" transient irritation, affecting only the conjunctiva. At a concentration of 20 percent in mineral oil, there was no irritation. Two formulations containing 2 and 6 percent Isopropyl Lanolate produced a minimal, transient irritation affecting

TABLE 4. Primary Skin Irritation

Test Material	Animal and No.	Concentration	Method	PII Score	Conclusion	References
Distilled Isopropyl Lanolate	Rabbit 3	Undiluted	Draize *et al.* Skin intact and abraded	0	Non-irritating.	CTFA, 1977
Distilled Isopropyl Lanolate	Guinea Pig 6	Undiluted	Draize *et al.* Skin intact and abraded	0	Non-irritating.	CTFA, 1977
Isopropyl Lanolate	Rabbit 6	Undiluted	Draize *et al.* Skin intact and abraded	0	Non-irritating.	Bio-Tox. Labs., 1970
Isopropyl Lanolate	Rabbit 6	Undiluted	Dept. of Transportation	0.2	Mild primary irritant. Erythema-eschar at 4 hrs. only	Bio-Tox. Labs., 1970
Isopropyl Lanolate	Rabbit 6	Undiluted	Draize *et al.*	1.54	Mild irritant. Erythema and eschar only; no edema.	Bio-Tox. Labs., 1974
Isopropyl Lanolate	Rabbit 6	Undiluted	Draize *et al.*	0.54	Mild irritant. Erythema and eschar only; no edema.	Food and Drug Res. Labs., 1974
Isopropyl Lanolate	Rabbit 6	Undiluted	Draize *et al.*	1.3	Mild irritant. Both erythema and edema at 24 & 72 hrs.	Food and Drug Res. Labs., 1973
Isopropyl Lanolate	Rabbit 6	Undiluted	Draize *et al.*	0.5	Mild irritant.	Food and Drug Res. Labs., 1973
Isopropyl Lanolate	Rabbit 6	Undiluted	Draize *et al.*	1.9	Mild irritant. Both erythema and edema at 24 & 72 hrs.	Food and Drug Res. Labs., 1973
Isopropyl Lanolate	Rabbit 6	Undiluted	Draize *et al.*	1.9	Mild irritant. Both erythema and edemat at 24 & 72 hrs.	Food and Drug Res. Labs., 1973

TABLE 5. Acute Eye Irritation

Test Material	No. of Rabbits	Methodology	Times of Observation	Mean Score	Conclusion	References
Distilled Isopropyl Lanolate	3, unwashed	Draize, undiluted	1 hr daily for 7 days	0	No irritation.	CTFA, 1977
	3, washed 2 sec.			0	No irritation.	
	3, washed, 4 sec.			0	No irritation	
Isopropyl Lanolate	3, unwashed	Draize, undiluted	1 hr & daily for 7 days	2.7 (at 1 day)	Slight hyperemia of conjunctiva.	Bio-Tox. Labs., 1970
	3, washed, 2 sec.			0	No irritation.	
	3, washed, 4 sec.			0	No irritation.	
Isopropyl Lanolate	6, unwashed	16 CFR 1500.42 undiluted	1, 2, 3, 7 days	7.7 (at 1 day)	Mild transient irritant, conjunctiva only; 7-day recovery.	Bio-Tox. Labs., 1974
Isopropyl Lanolate	6, unwashed	16 CFR 1500.42 undiluted	1, 2, 3, 7 days	7.0 (at 1 day)	Mild transient irritant, conjunctiva only; 7-day recovery.	Food and Drug Res. Labs., 1974
Isopropyl Lanolate (20% in mineral oil)	6, unwashed	16 CFR 1500.42 20%	1, 2, 3, 7 days.	0	No irritation.	Food and Drug Res. Labs., 1974
Isopropyl Lanolate	5, washed, 5 min.	Fed. Reg. 37, No. 83,	1 hr; 1,2,3,4,	1	"Marginal irritant."	Food and Drug Res. Labs., 1973
	3, washed, 24 hr.	1972; 0.1 ml each eye undiluted	7 days	1	Conjunctival redness, chemosis 1hr-1 dayonly.	
Isopropyl Lanolate	5, washed, 5 min.	Fed. Reg. 37, No. 83,	1 hr; 1,2,3,4,	1	"Marginal irritant."	Food and Drug Res. Labs., 1973
	3, washed, 24 hr.	1972; 0.05g in each eye undiluted	7 days	1	Conjunctival redness, chemosis 1hr-1day only.	Food and Drug Res. Labs., 1973
Isopropyl Lanolate	6, washed, 24 hr.	Fed. Reg., Sept. 17, 1964;(S191.12);0.1 ml undiluted	1, 2, 3 days	...	No Irritation	Food and Drug Res. Labs., 1973
Isopropyl Lanolate	6, washed, 24 hr.	Fed. Reg., Sept. 17, 1964;(S191.12); 100 mg	1, 2, 3 days	...	No irritation	Food and Drug Res. Labs., 1973
Skin care Cream Moisturizer 2% Isopropyl Lanolate)	6, unwashed	16 CFR 1500.42 0.1 ml 2%	1, 2, 3, 4, 7 days	...	Minimal irritation. Conjunctiva of 1 rabbit, at 24-48 hrs.	CTFA, 1978b.
	3, washed, 30sec.			...	Same, in 1 rabbit at 24hrs	
Makeup Concealer (6% Isopropyl Lanolate)	3-6	Draize 0.1 ml 6%	1 hr, daily for 3 days	...	Minimal irritation. Conjunctiva only, 1hr-1day.	CTFA, 1978b

only the conjunctiva. When the eyes were washed two to four seconds after application of Isopropyl Lanolate, no irritation resulted. If the eyes remained unwashed or if the washing was delayed for five minutes or 24 hours, some irritation usually occurred with the undiluted Isopropyl Lanolate. In one test on the unwashed eye, no evidence of irritation was seen (Bio-Tox. Labs., 1970, 1974; Food and Drug Res. Labs., 1974, 1973; CTFA, 1977, 1978b).

The results of these tests indicate that Isopropyl Lanolate has a very mild and transient irritation potential affecting the conjunctiva in the eye of the rabbit.

Subchronic

Dermal A 13-week dermal toxicity study of a cosmetic foundation product containing 5 percent Isopropyl Lanolate was conducted using female rats. In this test, 2000 mg/kg of the undiluted product was applied to the clipped backs of 15 rats once daily, 5 days a week, for 13 weeks (65 applications). Throughout this study, the test animals showed no adverse effects which could be attributed to the test material in the areas of behavior, appearance, body weight, hematology, skin condition, mortality, or histology (CTFA, 1977).

Special Studies

Skin Sensitization Distilled Isopropyl Lanolate was tested by the Landsteiner and Jacobs procedure in ten white male guinea pigs. A 0.1 percent solution of the test material in corn oil was injected intracutaneously on the shaved backs of the animals three times weekly for a total of 10 injections. the first injection was 0.05 ml and subsequent injections were 0.1 ml. Two weeks after the tenth injection, a challenge dose of 0.05 ml was administered. Corn oil was used in 10 control animals following the same procedure. As a result, a score of 1, indicating very slight erythema, was recorded for both experimental and control animals. The degree of sensitization was recorded as 0 for both corn oil and test material. It was concluded that distilled Isopropyl Lanolate was nonsensitizing in the guinea pig under these conditions (Bio-Tox. Labs., 1970).

Photosensitization Distilled Isopropyl Lanolate was tested for its photosensitization potential in 10 white male guinea pigs. First, the dose of ultraviolet light radiation was determined that had a sub-erythemal effect on the clipped backs of guinea pigs. The test material was applied daily for ten days and after each application the skin area was exposed for six hours to the pre-established intensity of ultraviolet light. Three control animals treated with distilled water were similarly irradiated. No evidence of photosensitization was observed in the experimental animals (Bio-Tox. Labs., 1970).

Clinical Assessment of Safety

Fifty-three human subjects, 18 years or older (race and sex not reported), were patch tested with Isopropyl Lanolate at concentrations of 20, 40, 60, and 80 percent in petrolatum, and at 100 percent in groups of 9, 13, 12, 8, and 11 individuals, respectively. Occlusive patches carrying the test material were

applied for 24 hours, four days per week for one week. At the end of the first week, all 53 subjects began to receive the 100 percent concentration which they continued to receive during the subsequent two weeks of testing. Throughout the three-week test period, a total of 12 applications and readings were scheduled for each individual. Skin irritation was scored on a scale from 0 to 4 and if any patch site developed a reaction of 2 or greater, the investigator could at his discretion, continue subsequent application on that same site or on a new site. Hence, in some individuals, more than four readings per week were taken. In application number 1, the test material did not elicit any visible evidence of irritation in any of the 53 individuals tested. In application numbers two through 12, the test material elicited evidence of irritation in six of the 53 individuals in the experiment.

Positive Subject #1: The subject scored a 1 reaction on the fifth application with 100 percent Isopropyl Lanolate with no recurrence of irritation on subsequent applications. All other scores prior to this were 0.

Positive Subject #2: The second subject scored a solitary minimal erythema (score = 1) following the twelfth application with 100 percent Isopropyl Lanolate. The erythema disappeared within 24 hours; all scores for this individual prior to this were 0.

Positive Subject #3: This subject showed a solitary minimal erythema (score = 1) after the fourth application; previous scores were 0 with 40 percent Isopropyl Lanolate. This disappeared within 24 hours with no recurrence of irritation on subsequent applications.

Positive Subject #4: This individual showed reactions during the first and third week which were suggestive of fatiguing. Scores recorded in the first week with 20 percent Isopropyl Lanolate were 0, 0, 1, and 2. Scores in the second week with 100 percent Isopropyl Lanolate were all 0, while scores in the third week, again with 100 percent Isopropyl Lanolate, were recorded as 0, 0, 0, 3, 1, 1.

Positive Subject #5: This subject scored 0 during the first week with 60 percent Isopropyl Lanolate and 0, 0, 1, 1, 0, 2, 2 during the second week with 100 percent Isopropyl Lanolate. During the third week at 100 percent Isopropyl Lanolate, three sites were scored; one site showed scores of 2, 2, 2, 1, 1, 0, a second site showed scores of 0, 3, 3, 3, and the third site indicated scores of 0, 3, 3, 3.

Positive Subject #6: This individual scored 0, 1, 1, 1, 1, 0 during the first week with 100 percent Isopropyl Lanolate. In the second week with 100 percent Isopropyl Lanolate, one site showed scores of 0, 2, 2, 1, 1, and a second site showed scores of 0, 2, 2, 1, 1. For the third week, the concentration was reduced from 100 to 80 percent at one site and to 40 percent at

> another. The site at which 80 percent Isopropyl Lanolate was used showed scores of 0, 1, 0, 3, 3, and the second site using a 40 percent concentration of the test material resulted in scores of 0, 1, 2, 0.

Thirty six days after the first application of Isopropyl Lanolate, all 53 subjects received a challenge test with 100 percent Isopropyl Lanolate. Two out of 53 subjects showed reactions suggestive of sensitization. These reactions were confirmed following second and third challenges. The investigator noted that these two individuals were hyper-reactive to many skin contactants, and he concluded that ". . .sensitization by this material under actual conditions of use would be a remote possibility, especially at lower concentrations" (CTFA, 1976a).

Another patch-test study of 16 human subjects was performed in which undiluted Isopropyl Lanolate was applied daily for 21 days. Fifteen of the 16 subjects completed the test with scores of zero. One of the 16 developed a reaction to the tape used to apply the patches. It was concluded that the material was non-irritating (CTFA, 1976b).

Three manufacturers of Isopropyl Lanolate in business for 12, 41, and 20 years, respectively, have no reports of adverse effects on employees nor have these firms received any reports of problems from customers (CTFA, 1978c).

The Schwartz-Peck prophetic patch test was performed on 104 humans (age, race and sex not given) using an oil treatment stick containing 14% Isopropyl Lanolate. Zero reactions occurred in all the first and second insult closed and open patch tests and after ultraviolet light exposure (CTFA, 1977).

The Draize-Shelanski repeated insult patch test elicited zero reactions in 50 subjects (not otherwise described) following the open, closed patch test and ultraviolet exposure using the same oil treatment stick. It was concluded that this product produced no irritation or sensitization reactions (CTFA, 1977).

A skin care cream moisturizer containing 2 percent Isopropyl Lanolate was applied five days a week to the backs of one male and 12 female subjects (aged 19 to 60 years) for 21 days. The test sites were observed and scored from 0 to 3 immediately prior to applying a fresh patch. One female, age 47, was scored 3 after the sixth patch and was not further exposed but was scored 3 throughout the remainder of the test. Total score for this individual was 49. The total skin irritation score for the remaining 12 individuals was 11. Six of these 12 individuals scored 0, three scored 1, one scored 2, and two individuals scored 3 (CTFA, 1977).

Human maximization tests were conducted with the same moisturizer on 25 subjects. The test procedures were conducted according to those described in the *Journal of Investigative Dermatology* 47(5):393-409, 1966. The test group consisted of 18 white females, aged 20-43; four white males, aged 21-38; and three black females, aged 20-25. No instance of allergic contact sensitization was noted (CTFA, 1977).

Non-occlusive patch tests were performed on 101 humans using a make-up concealer containing 6 percent Isopropyl Lanolate. No irritation was observed (CTFA, 1977).

SUMMARY

Isopropyl Lanolate is a mixture of the isopropyl esters of the lanolin fatty acids ranging from C_{12} through C_{34}. It is used in many types of cosmetic products which contact the skin, mucous membranes, and respiratory tract daily and over long periods of time.

Isopropyl Lanolate had an acute oral LD50 >40 g/kg in the rat, a very mild, transient primary irritant effect on the skin of the rabbit and guinea pig, and a slight promptly reversible irritant action on the conjunctiva of the eye of the rabbit. Skin sensitization and photosensitization tests were negative in the white guinea pig. The application of 2 g/kg of a formulation containing 5 percent Isopropyl Lanolate to the skin of rats five times a week for 13 weeks produced no harmful behavioral, systemic, or local effects on the skin.

Skin irritation studies in six humans were negative, with the exception of one study in which six out of 53 subjects showed some irritation at high concentrations. Human patch tests with formulations containing 6 and 14 percent Isopropyl Lanolate showed no irritation; one formulation containing 2 percent Isopropyl Lanolate "was very slightly irritating." None of the three formulations tested produced contact allergy sensitization. Results of one skin sensitization study indicated that 100 percent Isopropyl Lanolate was capable of acting in a manner consistent with that of a sensitizer in two individuals out of 53.

Though not critical to the assessment of its safety as currently used in cosmetics, it would be desirable to have information on the absorption and metabolism of Isopropyl Lanolate in rats both when given orally and when applied to the skin. Since Isopropyl Lanolate is used in aerosol form in some cosmetic formulations, tests for irritation of the respiratory tract should be conducted. In addition, the Panel expresses some concern about the occurence in one study of skin sensitization in two out of 53 subjects tested, and believes that further human studies for skin sensitization may be warranted.

CONCLUSION

On the basis of the information available, which the Expert Panel believes to have been accumulated in a reasonable manner, it is concluded that Isopropyl Lanolate is safe as currently used in cosmetic products.

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