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Final Report on the Safety Assessment of Jojoba Oil and Jojoba Wax

Jojoba Oil is obtained from seeds of the desert shrub, Jojoba *(Simmondsia chinensis)* and is used in cosmetic products at concentrations ranging from ≤ 0.1 % to 25.0%.

The oral LD_{50} for male rats is greater than 21.5 ml/kg. Results from short-term oral toxicity studies of Jojoba Oil indicated no treatment-related effects. Only slight conjunctival hyperemia was observed in the eyes of rabbits 1 h after the instillation of Jojoba Oil. Reactions had cleared by 24 h post-instillation.

No significant skin irritation reactions were observed in albino guinea pigs patch tested with undiluted Jojoba Oil. In a maximization test, no sensitization reactions were observed in 20 male and female albino marmots patch tested with 10.0% Jojoba alcohol.

A mixture of Jojoba Oil and hydrogenated Jojoba Wax was not mutagenic, with and without activation, in the Ames assay.

A topical oil product containing 0.5% Jojoba Oil and a lip balm product containing 20.0% Jojoba Oil were classified as nonirritants and nonsensitizers to humans. Sensitization reactions to undiluted Jojoba Oil were not observed in a group of 28 patients with no known sensitivities.

On the basis of the available animal and clinical data presented in this report, it is concluded that Jojoba Oil and Jojoba Wax are safe as cosmetic ingredients in the present practices of use and concentration.

INTRODUCTION

The toxicity of Jojoba Oil is reviewed in this report. The following data on Jojoba Oil derivatives (Jojoba Esters, Jojoba Wax, Jojoba Alcohols, and Jojobutter-51) have been included to support the safety assessment of Jojoba Oil in cosmetic products: acute oral toxicity, ocular irritation, skin irritation, skin sensitization, comedogenicity, phototoxicity, mutagenicity, and chemical data.

CHEMISTRY

Chemical and Physical Properties

Jojoba Oil, also known as Jojoba Liquid Wax, is defined as the oil expressed or extracted from seeds of the desert shrub, Jojoba (*Simmondsia chinensis*).[1] According to the Cosmetic, Toiletry and Fragrance Association (CTFA) Specification for Jojoba Oil, it consists almost

entirely of high molecular weight, straight-chain, monounsaturated alcohols (primarily C_{20}, C_{22} and C_{24}) and monounsaturated acids (primarily C_{18},C_{20}, C_{22} and C_{24}).[2] It has also been defined as a liquid wax ester with the generic formula, RCOOR".[3] RCO-represents oleic acid, eicosanoic acid (C20:1), and/or erucic acid (C22:1) moieties. R"O-represents eicosenyl alcohol (C20:1), docosenyl alcohol (C22:1), and/or tetracosenyl alcohol (C24:1) moieties.[3] The structural formula of an ester typically found in Jojoba Oil is as follows:[4]

$$CH_3(CH_2)_7CH = CH\text{-}(CH_2)_7CO\text{-}O\text{-}(CH_2)_{11}CH = CH(CH_2)_7CH_3$$

Jojoba Oil is composed almost completely (97%) of wax esters of monounsaturated, straight-chain acids and alcohols with high-molecular weights (C_{16}-C_{26}). These wax esters exist principally (83%) as combinations of C_{20} and C_{22} unsaturated acids and alcohols.[5] The long aliphatic chains of both the acids and alcohols make Jojoba Oil a highly lipophilic chemical.[6] The unsaturated acids are mixtures of *cis*-11 -eicosenoic acid(C_{20}) and *cis*-13-docosenoic acid (C_{22}); small quantities of oleic acid (C_{18}) and *cis*-15-tetracosenoic acid (C_{24}) are also present. The unsaturated alcohols are mixtures of *cis*-11-eicosenol, *cis*-13-docosenol, and *cis*-15-tetracosenol. Total free acids (C_{16} to C_{24}) and total alcohols (C_{16} to C_{26}) each account for 1% of the composition of Jojoba Oil. Small quantities of sterols (< 0.5%) are also present.[5]

Jojoba Oil is not easily oxidized and remains chemically unchanged for years.[5] It also remains essentially unchanged when heated repeatedly to temperatures above 285°C, or after being heated to 370°C for four days. The yellow color of Jojoba Oil disappears permanently when the oil is heated to 300°C over a short period of time. Additional properties of Jojoba Oil are listed in Table 1.

Jojoba esters are products of an interesterification of various ratios of Jojoba Oil and hydrogenated Jojoba wax. The physical consistency of these esters ranges from a semisolid paste to a liquid with properties that are almost identical to those of Jojoba Oil. The properties of two Jojoba esters are as follows: soft white to off-white appearance, typical fatty odor, saponification number of 90, iodine values of 60 and 40, and melting points of 29 and 58°C.[7]

Jojoba Wax is the product of complete reduction of the unsaturated alcohols and acids comprising the wax ester combinations of Jojoba Oil. It is a hard crystalline material with

Table 1. Properties of Jojoba Oil

Average molecular weight of wax esters	606	(40)
Form	Colorless to yellow liquid	(2)
Odor	Herbal to bland	(2)
Boiling point $_{757\ mm\ Hg}$ (Under N_2)	398°C	(40)
Melting point	6.8-7.0°C	(40)
Specific gravity (25°C)	0.860-0.870	(2)
Refractive index (25°C)	1.4630-1.4690	(2)
Viscosity (25°C)	58.4 cs	(9)
Solubility	Soluble in benzene, petroleum ether, chloroform, carbon tetrachloride, and carbon disulfide Immiscible with alcohol and acetone	(21)
Iodine value	78.0-88.0	(2)
Saponification value	88.0-98.0	(2)
Acid value	1.0 maximum	(2)
Titer of fatty acids	9.0-13.0°C (temperature range refers to solidification point of fatty acids resulting from saponification of the oil)	(2)

entirely of high molecular weight, straight-chain, monounsaturated alcohols (primarily C_{20}, C_{22} and C_{24}) and monounsaturated acids (primarily C_{18},C_{20}, C_{22} and C_{24}).[2] It has also been defined as a liquid wax ester with the generic formula, RCOOR*.[3] RCO-represents oleic acid, eicosanoic acid (C20:1), and/or erucic acid (C22:1) moieties. R*O-represents eicosenyl alcohol (C20:1), docosenyl alcohol (C22:1), and/or tetracosenyl alcohol (C24:1) moieties.[3] The structural formula of an ester typically found in Jojoba Oil is as follows:[4]

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Jojoba Wax has been mechanically formed into small spheres (150 to 450 microns) that are incorporated into exfoliating "scrub" products. Such products include facial scrub creams, body polishing lotions, abrasive soaps, and shower gels.[7]

Jojoba alcohols are used in cosmetics as agents to reduce slip resistance and as secondary emulsifiers that improve emulsion stability.[7]

Scope and Extent of Use in Cosmetics

The FDA cosmetic product formulation computer printout[14] is compiled through voluntary filing of such data in accordance with Title 21 part 720.4 of the Code of Federal Regulations.[15] Ingredients are listed in preset concentration ranges under specific product categories. Since certain cosmetic ingredients are supplied by the manufacturer at < 100% concentration, the value reported by the cosmetic formulator may not necessarily reflect the actual concentration found in the finished product; the actual concentration would be a fraction of that reported to the FDA. Data submitted within the framework of preset concentration ranges provide the opportunity for overestimation of the actual concentration of an ingredient in a particular product. An entry at the lowest end of a concentration range is considered the same as one entered at the highest end of that range, thus introducing the possibility of a two- to ten-fold error in the assumed ingredient concentration. Jojoba Oil is used in 188 cosmetic products at concentrations ranging from ≤ 0.1% to 25% (Table 2).[14]

Jojoba Oil has been approved for use in cosmetic formulations marketed in Japan.[16]

Table 2. Product Formulation Data for Jojoba Oil[14]

Product category	*Total no. of formulations in category*	*Total no. containing ingredient*	*No. of product formulations within each concentration Range (%)*				
			>10-25	>5-10	>1-5	>0.1-1	≤0.1
Hair conditioners, shampoo and other hair preparations	2931	62	1	3	2	13	43
Eye, ilp, and facial make-up products	1798	49	4	1	14	28	2
Nail products	46	3	-	-	-	1	2
Skin care products	3967	59	-	8	27	19	5
Miscellaneous cosmetic products	1542	15	-	1	6	6	2
1989 TOTALS		188	5	13	49	67	54

Surfaces to Which Applied

Cosmetic products containing Jojoba Oil are applied to most areas of the body, including the scalp and face, and may come in contact with the membranes of the eyes, nasal, and oral mucosae.

Frequency and Duration of Application

Products containing Jojoba Oil may be applied several times per day and can remain in contact with the skin for long periods of time.

properties that are comparable to carnauba and beeswax, and is miscible with polyethylene glycol in all proportions. The properties of Jojoba Wax are as follows: appearance of white to off-white free flowing hard wax flakes, slight fatty odor, saponification number of 90 to 95, iodine value of 1, and melting point of 69°C.[7]

Jojoba alcohols are prepared via the sodium reduction of Jojoba Oil and hydrogenated Joboba Wax. The alcohols are then further refined to render them suitable for use in cosmetics. The properties of Jojoba alcohols are as follows: specific gravity (25°C) of 0.8499, refractive index (20°C) of 1.4621, acid value of 0.01, saponification number of 0.75, hydroxy value of 178.4, iodine value of 83.1, and freezing point of 12°C.[7] Jojobutter-51 is an isomorphous mixture of Jojoba Oil, partially isomerized Jojoba Oil, and hydrogenated Jojoba Wax.[8]

Methods of Production

Jojoba Oil is obtained by pressing seed kernels from the evergreen desert plant *(Simmondsia chinensis)*, commonly known as the Jojoba shrub.[5]

Reactivity

The reaction of Jojoba Oil with sulfur yields a stable product; the liquidity of Jojoba Oil is not affected by this reaction. Jojoba Oil also readily undergoes hydrogenation in the presence of a variety of nickel catalysts. The crystalline, hydrogenated product formed has a melting point of approximately 70°C. The epoxidation of Jojoba Oil and the amidation of transesterified Jojoba Oil have also been reported.[5]

Analytical Methods

Jojoba Oil has been analyzed via the following methods: thin layer chromatography, gas chromatography, nuclear magnetic resonance spectroscopy, infrared spectroscopy, differential scanning calorimetry, and equivalent carbon number analyses.[9,10]

Impurities

The CTFA specification for Jojoba oil defines positive identification of Jojoba Oil as a close match to the infrared (IR) spectrum, with no indication of foreign materials.[2]

The specification for crude Jojoba Oil includes 0.8 ppm elemental lead (Pb) and less than 0.I ppm arsenic (As_2O_3).[11]

When Jojoba Oil was refined via a standard alkali refining process,[12] a trace amount of nitrogen-containing compounds (6.0 ± 2 ppm) was found.[10] Data on the presence and nature of terpenoid compounds were not available.

Jojoba alcohols contain less than 20 ppm lead and less than 2 ppm arsenic.[7]

USE

Purpose in Cosmetics

Jojoba Oil is used as a skin conditioning agent (occlusive) and as a hair conditioning agent.[13]

Jojoba esters are used as emollients in creams, lotions, and stick products.[7]

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Products containing Jojoba Oil may be applied several times per day and can remain in contact with the skin for long periods of time.

Non-Cosmetic Use

Non-cosmetic uses of Jojoba Oil are as follows:[9] (1) high-temperature lubricant for high-speed machinery, (2) sulfurization for extreme-pressure lubricants, (3) treatment of leather, (4) benzene or gasoline-soluble factice for rubber, varnishes, linoleum, or chewing gum, and (5) hydrogenation into hard wax for use as polishing wax, in carbon paper, or as candles that give a brilliant flame with no smoke. Jojoba Oil is also used in the pharmaceutical industry as an antifoaming agent in the fermentation of tetracycline and penicillin,[17] and as a substitute for sperm whale oil.[18]

BIOLOGICAL PROPERTIES

Effect on Blood Cholesterol

The effects of ingested Jojoba Oil on blood cholesterol concentrations were evaluated using four groups of female New Zealand white rabbits (4 months old; 4 rabbits per group). The following diets (100 g of chow per diet) were provided daily for 30 days: chow supplemented with 2% Jojoba Oil (Group 1), chow containing 1% cholesterol and 2% Jojoba Oil (Group 2), chow containing 1% cholesterol supplemented with 6% Jojoba Oil (Group 3), chow supplemented with 1% cholesterol (cholesterol control), and untreated chow (negative control). Uneaten chow was discarded each day. The study was repeated using different groups of rabbits. Blood cholesterol concentrations were slightly elevated in rabbits fed a cholesterol-free diet containing 2% Jojoba Oil. Rabbits fed an atherogenic diet consisting of 1% cholesterol and 2% Jojoba Oil had a 40% reduction in blood cholesterol over that of the cholesterol control. There was no further reduction in blood cholesterol concentrations in rabbits fed a diet containing 1% cholesterol and 6% Jojoba Oil for an additional 30-day period.[19]

Absorption, Distribution, Metabolism, and Excretion

The absorption and distribution of Jojoba Wax, semisolid fraction of Jojoba Oil, was evaluated using 24 male albino mice (5 weeks old; 25-30 g). The animals were divided equally into four groups and [^{14}C]Jojoba Wax (90 $\pm$ 10 mg; specific activity 1.14 μCi/g) was injected subcutaneously into the right leg of each animal. Randomly labeled Jojoba Wax was obtained by exposure of fruiting branches of the shrub (*Simmondsia chinensis*) to $^{14}CO_2$ fluxes. The four groups of animals were sacrificed 1, 8, 15, and 23 days after injection, and radioactivity in the testis, skin, carcass, and lipid and aqueous fractions of the brain and liver was counted. The results indicated that only a small fraction of the injected [^{14}C]Jojoba Wax was absorbed. At day 1 post-injection, most of the [^{14}C]Jojoba Wax was detected in the carcass and in lipid fractions of the brain and liver. In the brain lipid fraction, the amount of [^{14}C]Jojoba Wax decreased from 108 $\pm$ 46 μg (day 1) to 9 $\pm$ 4 μg (day 23), and, in the liver lipid fraction, from 57 $\pm$ 16 μg (day 1) to 15 $\pm$ 7 μg (day 23). The amount of [^{14}C]Jojoba Wax in the carcass (l00 $\pm$ 4 g) was determined on day 1, but not on day 23.[20]

In a second experiment, 10 albino mice (5 males, 5 females) were injected subcutaneously with [^{14}C]Jojoba Wax (same dose and specific activity) and sacrificed 90 days after injection. Most of the ^{14}C Wax (.08 $\pm$ .016 μg; > 99%) was detected in the carcass. At 8 and 23 days post-injection, the radioactivity thin-layer chromatography profile of carcass lipids indicated that

75 to 83% of the ^{14}C remained in the lipid form in which it had been injected. The remaining ^{14}C was incorporated mainly into neutral lipids, such as triglycerides and fatty acids.[20]

The absorption and distribution of radioactivity from [^{14}C]Jojoba Wax were further evaluated using 21 male albino mice (5 weeks old; 25-30 g). In this study, the specific activity of [^{14}C]Jojoba Wax was greater than that used in the preceding two experiments. The animals were divided equally into three groups, and [^{14}C]Jojoba Wax was injected subcutaneously into the neck at doses of 9, 23, and 120 mg. Animals were sacrificed 8 days after injection. Following the injection of each dose, radioactivity was detected in the liver, brain, testes, lungs, heart, spleen, kidneys, and carcass lipids, but not in the skin or epididymal fat. The greatest counts of radioactivity were frequently detected in the liver, brain, lungs, and carcass lipids. The smallest amount of radioactivity (all organs included) was detected in the animals injected with 9 mg of [^{14}C]Jojoba Wax. There were no significant differences between counts of radioactivity in animals injected with 23 mg and those given 120 mg of [^{14}C]Jojoba Wax.[20]

Jojoba Oil was detected in the feces of dd Y-S mice (5-week-old) one week after the mice were force-fed doses of 0.5, 0.75, 1.13, and 1.69 mg/10 g. Four groups of 20 mice were evaluated.[11]

TOXICOLOGY

Acute Oral Toxicity

Following the administration of Jojoba Oil (21.5 ml/kg) to male albino rats (number and weights not stated), fewer than 50% of the animals died.[21]

The acute oral toxicity of a lip balm product containing 20.0% Jojoba Oil was evaluated using 10 Sprague-Dawley rats (5 males, 5 females; weights not stated). A single oral dose (5.0 g/kg) was administered to each animal via gavage. The animals were fasted during the night prior to dosing. None of the animals died during the l5-day observation period, and the product was classified as nontoxic.[22]

In another study, the acute oral toxicity of two Jojoba esters (iodine values 40 and 60) was evaluated using two groups of 10 white rats (5 males, 5 females per group), respectively. Animal weights ranged from 208 to 238 g in one group and from 212 to 238 g in the other group. Feed was withheld for 18 h, and the test substance (dose = 5.0 g/kg) was administered via a rigid stomach tube. The animals were then observed for signs of toxicity during a period of 14 days; all of the animals survived. At the conclusion of the observation period, the animals were sacrificed and internal organs were examined microscopically. No gross abnormalities were observed in either test group.[7]

The acute oral toxicity of a 50.0% solution of Jojoba Wax in corn oil (dose = 5.0 g/kg) was evaluated according to the procedure described above using 10 albino Sprague-Dawley rats (5 males, 5 females; 200-300 g). The only procedural variation was a four-day observation period after dosing. Jojoba Wax was not classified as a toxic substance. Neither the mortality rate nor the results of macroscopic examinations were reported.[7]

The acute oral toxicity of Jojoba alcohol was evaluated using three groups of 20 mice of the dd Y-S strain (weights not stated). The test substance was administered via stomach tube to the three groups at doses of 32, 40, and 50 ml/kg, respectively. None of the animals in any of the three groups died.[23]

Short-Term Oral Toxicity

The oral toxicity of crude Jojoba Oil was evaluated using 80 five-week-old, dd Y-S mice. The average weights of 40 male and 40 female mice were 22.5 and 21.3 g, respectively. The animals were divided equally into four groups (10 males, 10 females/group), and Jojoba Oil was administered via gastric intubation at doses of 0.5, 0.75, 1.13, and 1.69 ml/10 g of body weight. Feed was withheld 6 h prior to intubation. At 7 days post-administration, the animals were sacrificed and necropsied. Peritonitis was observed in one animal dosed with 1.69 ml/10 g, and discoloration of the renal capsule was observed among all groups. None of the gross alterations observed, including the single death, was attributed to the administration of Jojoba Oil. The actual causes of these reported effects were not reported.(11)

In another study, the oral toxicity of refined Jojoba Oil was evaluated using four groups of 10 male Sprague-Dawley rats (avg. weight 80.6 g). Two of the groups were fed basal diets (5 g/feeding) containing 0.5 and 1.0 g of Jojoba Oil, respectively, once daily for seven days. The remaining two groups were fed basal diets containing 2.0 and 3.0 g of Jojoba Oil, respectively, once daily for four days. The animals were given water *ad libitum*. Signs of toxicity were observed in five of the mice that were fed 1.0 g of Jojoba Oil (in diet) and all of the mice fed 2.0 and 3.0 g of Jojoba Oil. The mortality rate was 10% in each of these three groups. None of the mice fed 0.5 g of Jojoba Oil died.(10)

Short-Term Subcutaneous Toxicity

The dermal toxicity of Jojoba Wax (semisolid fraction of Jojoba Oil) was evaluated using three groups of 6-week-old male rats (10 rats/group). The two experimental groups received subcutaneous injections of Jojoba Wax (1 ml/kg of body weight) 6 days per week for 7 weeks. Refined olive oil was administered to the control group according to the same procedure. At the end of the seventh week, 10 experimental animals and five controls were terminated. The remaining animals were sacrificed six weeks later. Urine tests, blood tests, and gross and microscopic examinations were performed. There were no traces of bilirubin, ketones, glucose, or urobilinogen in the urine of any of the tested animals. Occult blood was detected in the urine of 7 experimental animals and 5 controls. Additionally all experimental animals and 5 controls had proteinuria. The urinary protein could have resulted from the contamination of urine with traces of feed. Most of the results from blood chemistry and blood cell analyses were similar in experimental and control groups. Except for a slight increase in liver weight relative to the increase in body weight (experimental animals), there were no significant differences in body weight or organ weight between experimental and control groups. Microscopic changes were not observed in the skin or in any of the other organs examined.(24)

Subchronic Dermal Toxicity

The subchronic dermal toxicity of refined Jojoba Wax (semisolid fraction of Jojoba Oil) was evaluated using 32 DH guinea pigs (320 ± 25 g). The animals were divided into four groups (4 males, 4 females/group). In the first two groups, Jojoba Wax was applied to shaved dorsal skin in doses of 0.25 and 0.5 g/kg, respectively. Applications were made 6 days per week for a

total of 20 weeks. The application sites were not covered. The two control groups received applications of olive oil (0.5 g/kg) and saline, respectively, according to the same procedure. At the end of the treatment period, the animals were sacrificed and gross and microscopic examinations were performed. There were no significant differences in body weight or organ weight (liver, heart, kidneys, and testes) between the four groups of guinea pigs. Furthermore, lesions were not observed in tissues from the following organs (all groups): adrenal glands, thyroid glands, kidneys, urinary bladder, spleen, liver, pancreas, heart, brain (two sections), stomach, small and large intestines, and skin from treated and untreated areas.[24]

Ocular Irritation

The ocular irritation potential of refined Jojoba Oil was evaluated using six male white rabbits. Immediately after the oil (0.1 ml) was instilled into the conjunctival sac of the right eye of each animal, slight atretoblepharia was observed. Slight conjunctival hyperemia was observed 1 h after instillation. Ocular irritation did not increase in severity, and all reactions had cleared by 24 h post-instillation.[11]

The ocular irritation potential of a lip balm product containing 20.0% Jojoba Oil was evaluated using six New Zealand white rabbits. The test substance (0.1 ml) was instilled once into the conjunctival sac of one eye. The untreated eye served as the control. Reactions were scored at 24, 48, and 72 h post-instillation according to the Draize scale. At 24 h post-instillation, the mean ocular irritation score was 0.3 ± 0.8. No reactions were observed at 48 and 72 h. The product was classified as a nonirritant.[25]

In another study, the ocular irritation potential of two Jojoba esters (iodine values 40 and 60, respectively) was evaluated using two groups of six albino rabbits (ages not stated), respectively. The test substance (O.1 ml) was instilled, as received, into the right eye of each animal. Untreated eyes served as controls. Reactions were scored at 24, 48, and 72 h post-instillation according to the following scales: corneal opacity scores of 0 (no ulceration or opacity) to 4 (complete corneal opacity, iris not discernible); scores for the iris of 0 (normal) to 2 (no reaction to light, hemorrhage, gross destruction; any or all of these); conjunctival redness scores of 0 (vessels normal) to 3 (diffuse, beefy red); conjunctival chemosis scores of 0 (no swelling of the lids and/or nictitating membrane) to 4 (swelling with lids more than half closed); conjunctival discharge scores of 0 (no discharge) to 3 (discharge with moistening of the lids and hairs, and considerable area around the eye). In accordance with Title 16 part 1500.42 of the Code of Federal Regulations,[26] test results were classified as positive only if four or more animals had positive reactions in the cornea, iris, and conjunctiva, and, negative, if only one animal had positive reactions in the cornea, iris or conjunctiva. Of the two groups of rabbits tested, 1 of 6 had a reaction to one of the esters (iodine value = 60) and 4 of 6 had reactions to the other ester (iodine value = 30). All of the reactions were classified as conjunctival redness (diffuse, crimson red; individual vessels not easily discernible). As the test ingredient did not produce a positive reaction in four or more test animals, it would not be classified as an eye irritant.[7]

The preceding experimental procedure was used to evaluate the ocular irritation potential of Jojoba Wax in six albino rabbits (ages not stated). The only procedural variation was the instillation of 0.05 ml of test substance. The following reactions were observed in 3 of the 6 rabbits tested: conjunctival chemosis, obvious swelling with partial eversion of lids (1 rabbit), and conjunctival redness, diffuse crimson red conjunctiva in which individual vessels were not

discernible (2 rabbits). As the test ingredient did not produce a positive reaction in 4 or more test animals, it would not be classified as an eye irritant.[7]

The ocular irritant potential of 12.5, 25.0, and 50% Jojoba alcohol (in refined Jojoba Oil) was evaluated using three groups of three rabbits, respectively, according to the procedure by Draize. The test substance (0.05 ml) was instilled into the conjunctival sac of the right eye of each animal, and the untreated left eye served as the control. There were no reactions in the cornea or iris in any of the animals tested. Reactions in the conjunctiva were observed, but not beyond 24 h post-instillation. At concentrations of 12.5 and 50.0% Jojoba alcohol, conjunctival reactions decreased in severity from Draize scores of 1.3 to 0.7 and from Draize scores of 4.0 to 0.7, respectively, up to 24 h post-instillation. At a concentration of 25.0%, reactions with a Draize score of 2 persisted up to 6 h post-instillation.[23]

Skin Irritation

The skin irritation potential of refined Jojoba Oil was evaluated using 10 male albino guinea pigs (weights = 350 g; strain not stated). Olive oil and light liquid paraffin served as controls. Half of the animals were simultaneously patch tested with Jojoba Oil (0.5 ml) and each control (0.5 ml) daily for 15 days. Applications were made to shaved skin. The remaining animals were patch tested (same procedure) daily for 30 days. Reactions were scored according to the Draize[27] scale: 0 (no erythema or edema) to 4 (severe erythema to slight eschar formation, and edema). No significant reactions to Jojoba Oil or olive oil were observed. However, flare reactions to liquid paraffin were observed on the third day of the study. The results of microscopic examinations indicated no edema or cellular infiltration. However, swelling of the epidermis and hypertrophy at the roots of hairs were evident in both groups. Swelling of the epidermis may have been due, in part, to the shaving of application sites.[11]

The skin irritation potential of lip balm product containing 20.0% Jojoba Oil was evaluated using six New Zealand white rabbits. A single 24 h application of the test substance (0.5 ml) was made to abraded and intact skin of the back. The test sites were covered with occlusive patches during the 24 h period. At 24 and 72 h post application, reactions (erythema and edema) were scored according to the Draize scale: 0 to 4. The product was considered minimally irritating (mean primary irritation score = 0.33).[28]

In another study, the skin irritation potential of two Jojoba esters (iodine values = 40 and 60) was evaluated using two groups of six albino rabbits (ages not stated), respectively. Prior to application of the test substance, 10.0% of the body area of each animal was clipped free of hair. The test substance (0.5 ml) was applied to abraded and intact skin sites on the back. The esters were applied as received. The application sites (abraded and intact) were covered with a 1" x 2" patch that was sealed with transparent tape. The entire treatment area was also wrapped with a sheet of polyethylene that was secured with tape. At 24 h post-application, the patches were removed and excess test material was wiped from each test site. Reactions were then scored at 24 and 72 h post-application according to the scales: 0 (no erythema) to 4 (severe erythema to eschar formation) and 0 (no edema) to 4 (severe edema). Primary irritation scores of 5 or greater were defined as positive skin irritation reactions. The primary irritation scores for the two esters were 0.42 and 1.08, respectively.[7]

The preceding experimental procedure was used to evaluate the skin irritation potential of Jojoba Wax in six albino rabbits (ages not stated). Positive skin irritation reactions were defined as primary irritation scores of 5 or greater. The primary irritation score for Jojoba Wax was 0.17.[7]

The skin irritation potential of Jojoba alcohol was evaluated using 10 white male rabbits. Jojoba alcohol was tested at concentrations of 12.5, 25.0, and 50.0%, (in refined Jojoba Oil). Oleyl alcohol, also tested at concentrations of 12.5, 25.0, and 50.0% (in refined Jojoba Oil), served as the control. Each animal was simultaneously patch tested (6 patches per animal) with the three concentrations of both the test substance and control; patches were applied to the back. The two repeated patch tests performed involved l5 days of patch testing (5 rabbits) and 30 days of continuous patch testing (5 rabbits); respectively. Naked eye observations of reactions were made, according to the method of Draize, on the last day of each test.

In 15 and 30 day tests, there were no reactions to 12.5% Jojoba alcohol that were grossly visible. However, the results of microscopic examinations were that reactions ranged from very light to light incrassation of the germinative zone of the epidermis in four rabbits (l5 day test), and reactions ranging from very light to medium incrassation of the germinative zone and very light to light dermal infiltration in four rabbits (30 day test). Also, in the l5 day test, 25.0% Jojoba alcohol induced redness (2 rabbits), and redness and induration (1 rabbit); 50.0% Jojoba alcohol induced redness (1 rabbit), redness and induration (2 rabbits), and redness, induration, and swelling (1 rabbit). In the 30 day test, 25.0% Jojoba alcohol induced redness (2 rabbits); 50.0% Jojoba alcohol induced redness (2 rabbits) and redness, induration, and swelling (2 rabbits).

Histopathological evaluations in both the 15 and 30 day tests were negative for any reactions that were more severe than light incrassation of the germinative zone of the epidermis or very light dermal infiltration. The average skin irritation scores during the l5 day test were as follows: 12.5% Jojoba alcohol (no reactions), 25.0% Jojoba alcohol (0.2-0.8), and 50.0% Jojoba alcohol (0.4-1.80). During the 30 day skin irritation test, the average skin irritation scores were as follows: 12.5% Jojoba alcohol (0.5), 25.0% Jojoba alcohol (0.2 to 1.0), and 50.0% Jojoba alcohol (0.6 to 1.25). The results of skin irritation tests on 12.5, 25.0, and 50.0% Jojoba alcohol were not considered different from those for the controls, 12.5, 25.0, and 50.0% oleyl alcohol.[23]

The primary skin irritation potential of Jojoba alcohol (10.0% w/w in refined Jojoba Oil) was evaluated using 10 male and 10 female albino marmots. Patch tests were conducted according to the procedure of Draize.[27] The test substance (0.5 ml) was applied, under a one-inch patch secured with adhesive tape, to each animal. The animals were immobilized in an animal holder, and the entire trunk of each animal was wrapped with rubberized cloth that remained throughout the 24 h exposure period. Reactions were scored at 24 and 48 h post-application according to the scales: 0 (no erythema) to 4 (severe erythema to slight eschar formation); 0 (no edema) to 4 (severe edema). Reactions to the test substance were not observed in any of the animals tested.[23]

In another study, the skin irritation potential of Jojobutter-51 was evaluated using six male New Zealand white rabbits (2.3-3.0 kg). The test substance (0.5 ml, acid value = 2.8) was applied via gauze patches to abraded and intact sites (clipped free of hair) lateral to the midline of the back. The trunk of each animal was then wrapped with occlusive patches of polyethylene; patches and polyethylene coverings were secured with hypoallergenic tape for 24 h. Immediately after patch removal, excess test material was wiped from the skin with gauze. Reactions were scored at 24 and 72 h post-application according to the Draize[27] scale: 0 (no erythema or edema) to 4 (severe erythema to slight eschar formation, and edema). At 24 h post-application, the following reactions were observed: no erythema (2 rabbits), very slight erythema (2 rabbits), and well-defined erythema (2 rabbits). Jojobutter-5l (acid value = 2.8) was classified as a mild irritant (Primary Irritation Index = 0.5). When samples of Jojobutter-51

with a reduced acid value (1.6) were applied to an additional six rabbits according to the same procedure, erythema was not observed. However, slight edema was observed at the abraded site of one rabbit at 24 h post-application. Jojobutter (acid value = 1.6) was classified as a nonirritant (Primary Irritation Index = 0.04).[8]

Comedogenicity

The comedogenicity of a Jojoba ester (iodine value = 60) was evaluated according to the method of Morris and Kwan[29] using four young adult New Zealand white rabbits. Three animals were treated with the test substance and one animal was treated with the positive control, isopropyl myristate. The test substance (5 ml) was added to 45 ml of mineral oil, and the solution was heated to a temperature of 70°C. Liberal applications of the test solution were made to the right external ear canal via a cotton-tipped applicator 5 days per week (once per day) for a total of 14 applications. After each application, the solution was rubbed into the skin with a glass rod. The untreated left ear served as the negative control. At the end of the application period, the animals were sacrificed and treated and untreated external ears were removed, fixed in 10.0% buffered formalin, and evaluated histopathologically. Comedone formation was graded according to the scale: 0 (negative) to 5 (severe: widely dilated follicles filled with packed keratin, follicular epithelial hyperplasia causing partial or total involution of sebaceous glands and ducts; possible inflammatory changes). The test solution was noncomedogenic (score = 0), whereas, the positive control caused marked superficial acanthosis and hyperkeratosis.[30] When another Jojoba ester (iodine value = 40) was evaluated according to the same procedure, the comedogenicity score was 0.65, classifying the test substance as between non-comedogenic and slightly comedogenic.[31]

The comedogenicity of Jojoba Wax also was evaluated according to the procedure described immediately above. The comedogenicity score was 2.67, classifying the test substance as moderately comedogenic.[32]

Skin Sensitization

The skin sensitization potential of Jojoba alcohol (10.0% w/w in refined Jojoba Oil) was evaluated according to the maximization test using 10 male and 10 female albino marmots. Two groups of male and female marmots (10 animals per sex) served as the untreated controls. Initially, each of the following substances (0.05 ml) was injected at different paired sites, to the right and left of the midline, on the back of each animal: complete adjuvant/water (1/1 mixture), Jojoba alcohol solution, and complete adjuvant/Jojoba alcohol solution (1/1 mixture). The Jojoba alcohol solution consisted of Jojoba alcohol dissolved in refined Jojoba Oil (1/10 mixture). After one week, patches containing the 10.0% Jojoba alcohol solution (0.5 ml) were applied to the same injection sites. Two weeks later (challenge phase), a patch containing the solution was applied to a new site that was posterior to the injection sites. No sensitization reactions were observed 24 or 48 h after application of the challenge patch.[23]

Mutagenicity

The mutagenicity of Jojoba alcohol was evaluated according to the preincubation method by Yahagi et al.[33] using *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537, and TA1538 and *Escherichia coli* strain WP-2 *(uvr* A). All strains were tested with

concentrations of Jojoba alcohol ranging from 1.25 to 40.0 nl/plate both with and without metabolic activation. Untreated cultures of each strain tested served as negative controls. The following chemicals served as positive controls: *N-ethyl-N-nitro-N*-nitrosoguanidine (strains TA100, TA1535, and WP-2 (uvr A) without activation), benzo(a)pyrene (strains TA98, TA100, TA1537, and TA1538 with activation), 2-aminoanthracene (strain WP-2 (uvr A) with activation), 2-nitroflourene (strain TA98 without activation), 9-aminoanthracene (strain TA1537 without activation), and 4-nitro-o-phenylenediamine (strain TA1538 without activation).

The highest numbers of revertants per plate, compared with controls, in each strain tested without activation were as follows: TA98 (1.5 x control, dose = 10 nl/plate), TA100 (1.2 x control, 10 nl/plate), TA1535 (2.7 x control, 20 nl/plate), TA1537 (1.4 x control, 40 nl/plate), TA1538 (1.8 x control, 20 nl/plate), and WP-2 *(uvr* A) (1.8 x control, 1.25 and 20 nl/plate). The highest numbers of revertants per plate, compared with controls, in each strain tested with activation were as follows: TA98 (1 x control, 2.5 nl/plate), TA100 (1 x control, 40 nl/plate), TA1535 (1 x control, 1.25 and 20 nl/plate), TA1537 (1.5 x control, 10 nl/plate), TA1538 (1.2 x control, 2.5 nl/plate), and WP-2 (uvr A) (1.2 x control, 5.0 and 40 nl/plate). In positive control cultures, the number of revertants per plate ranged from 3.2 to 41.7 times that of control cultures. The authors concluded that Jojoba alcohol was not mutagenic.[23]

The Ames test[34] was used to evaluate the mutagenicity of two samples of Jojobutter-51 in strains TA97, TA98, TA100, and TA102 of *S. typhimurium.* The test substance (in tetrahydrofuran) was evaluated at concentrations ranging from 1 to 1000 µg/plate with and without metabolic activation. The concentration of rat liver homogenate used for metabolic activation in the bioassay was 84 µg protein per plate. Tretahydrofuran served as the solvent control, and positive controls were as follows: sodium azide, 2-nitrofluorene, 9-aminoacridine, methyl methane sulfonate, and 2-aminofluorene. Jojobutter-51 was not mutagenic at any of the concentrations tested. All of the positive controls were mutagenic; the solvent control was not mutagenic. Jojobutter-51 also was not mutagenic in a second bioassay (same procedure and test concentrations) in which the concentration of rat liver homogenate was increased to 140 µg per plate, or in the absence of metabolic activation. With the exceptions of methyl methane sulfonate and 9-aminoacridine, results with negative and positive controls were similar to those reported in the first bioassay.[35]

CLINICAL ASSESSMENT OF SAFETY

Skin Irritation

The skin Irritation potential of refined Jojoba Oil and crude Jojoba Oil was evaluated using 26 patients (I8-59 years old) with histories of eczema or dermatitis. Olive oil, safflower oil, and white petrolatum served as controls. The test substances were applied to the upper back for 48 h via adhesive bandages. Reactions were scored 30 min and 24 h after patch removal. Slight eczema, the only reaction reported, was observed in one of the patients patch tested with crude Jojoba Oil. This reaction was not observed 24 h after patch removal. In another skin irritation study (same procedure), both test substances and controls were applied to 20 patients (19-42 years old) with histories of eczema or dermatitis. Positive reactions to crude Jojoba Oil and olive oil (1 patient) were observed 30 min after patch removal. Positive reactions to refined

Jojoba Oil, safflower oil, and white petrolatum (1 patient) were observed 30 min and 24 h after patch removal. Both patients were thought to have been inherently hyperallergic.[11]

In a clinical use test, a lip balm product containing 20.0% Jojoba Oil was applied to the lips of 200 adult female subjects daily for 4 days. The subjects were evaluated at baseline and at 2 and 4 weeks post-application for signs of subjective/objective irritation. No adverse reactions were noted at any time during the study.[36]

The skin irritation potential of Jojoba alcohol was evaluated using 60 human subjects. Twenty subjects (healthy skin) were patch tested with 10.0 and 100.0% Jojoba alcohol, and 40 subjects (contact dermatitis patients) were patch tested with 100.0% Jojoba alcohol. Oleyl alcohol, at concentrations of 10.0% (normal subjects) and 100.0% (patients), served as the control. Patches containing the test substance were applied to the upper back for 48 h. Reactions were scored 30 min and 24 h after patch removal according to the scale: 0 to 4+. In the group of healthy subjects, one reaction (± reaction to 10.0% Jojoba alcohol) was observed at 30 min; no reactions were observed at 24 h. There were no reactions to l00.0% Jojoba Oil in healthy subjects. In the group of patients, one reaction (± reaction to 100.0% Jojoba alcohol) was observed at 30 min; no reactions were observed at 24 h. The reactions observed in the patient control group included one reaction (± reaction to 100.0% oleyl alcohol) at 30 min and no reactions at 24 h. There were no reactions to 10.0% oleyl alcohol in the healthy group of control subjects. Jojoba alcohol was not a skin irritant.[23]

Skin Irritation and Sensitization

The skin irritation and sensitization potential of a lip balm product containing 20.0% Jojoba Oil was evaluated using 208 adult female subjects. The test substance (0.2 g) was applied for 24 h to the back of each subject, between the scapulae and waist (adjacent to the midline), via an occlusive patch. Applications were made three times per week for a total of three weeks. Patch removals on Tuesdays and Thursdays were followed by 24 h nontreatment periods, and those on Saturdays were followed by 48 h nontreatment periods. Reactions were scored prior to the next patch application according to the scale: 0 (no evidence of any effect) to 4 (deep red erythema with vesiculation or weeping). The application site was changed if a subject had a reaction of 2 (uniform, pink-red erythema) or greater during induction. If a 2+ reaction was observed at the new site, induction application were discontinued. However, all subjects with induction reactions were patch-tested during the challenge phase. After a 10-19 day nontreatment period, a challenge patch was applied for 48 h to a new site. Reactions were scored at 48 and 72 h post-application. Mild, transient irritation, nonspecific in nature, was observed in one subject. The product was classified as a nonirritant and a nonsensitizer.[37]

The skin irritation and sensitization potential of a topical oil product containing 0.5% Jojoba Oil was evaluated in the modified Draize-Shelanski repeat insult patch test using 152 normal subjects (38 males, 114 females; 18-65 years old). The test substance (on occlusive patch) was applied to the upper back of each subject on Monday, Wednesday, and Friday for three consecutive weeks. Sites were scored 24 h after patch removal according to the scale: 0 (no reaction) to + + + + (bullae or extensive erosions involving at least 50% of the test area). After a two-week nontreatment period, two challenge patches were applied consecutively to new sites (adjacent to old site) for 48 h. Sites were scored at 48 and 96 h. None of the subjects had allergic reactions. The product was neither a clinically significant irritant nor a sensitizer.[38]

A total of six patients who were suspected of being sensitive to Jojoba Oil were tested in a contact dermatitis study. The patients were patch tested (muslin patches) with each of the following: (1) 20% Jojoba Oil mixed with 80% olive oil, (2) 20% Jojoba Oil mixed with 80% liquid petrolatum, (3) pure olive oil, (4) pure mineral oil, and (5) muslin only. Positive reactions (erythema or erythema and vesicles) to both Jojoba Oil mixtures were observed on the forearms of five patients within 24 or 48 h after patch application. None of the patients had reactions to olive oil, mineral oil, or muslin. When the patient with no reaction to Jojoba oil mixtures subsequently used pure Jojoba Oil as a hairdressing, contact dermatitis of the scalp resulted. Reactions were not observed in a control group of 28 patients patch tested (muslin patches) with pure Jojoba oil. These patients had no known sensitivities.[18]

Phototoxicity

The phototoxicity of a lip balm product containing 20.0% Jojoba Oil was evaluated using 10 subjects. In half of the subjects, approximately 0.2 g of the test substance was applied for 24 h to the inner aspect of the right forearm, and in the remaining half, to the inner aspect of the left forearm. Similarly, the nonirradiated control site was on the inner aspect of the right or left forearm. After patch removal, reactions were scored according to the scale: 0 (no evidence of any effect) to 4 (deep red erythema with vesiculation or weeping). The test sites were then irradiated for 15 min with UVA light (dose = 4,400 $\mu W/cm^2$) at a distance of approximately 10 cm. In each subject, the nonirradiated control site was shielded with aluminum foil during irradiation of the test site. Reactions were scored at the end of exposure and 24 and 48 h later. None of the subjects had reactions, and the product was classified as nonphototoxic.[37]

A total of 102 female subjects (18-49 years old) participated in an outdoor use test. Each subject used a sunscreen oil containing 0.5% Jojoba Oil for 2 h (in sunlight) on two consecutive days. The subjects were evaluated at 24 and 48 h post-exposure. Three subjects experienced slight, transient discomfort that was considered to be clinically insignificant.[39]

The phototoxicity of Jojoba alcohol was evaluated using 60 subjects. Twenty subject (healthy skin)were patch tested with10.0% and 100.0% Jojoba alcohol, and 40 subjects (contact dermatitis patients) were patch tested with 100.0% Jojoba alcohol. Oleyl alcohol, at concentrations of 10.0% (normal subjects) and 100.0% (patients), served as the control. Patches containing the test substance were applied to the upper back for 48 h. Each test site was then irradiated with the minimal erythema dose of black light. Neither the duration of exposure nor the intensity of the light source was stated. Reactions were scored at 24 h intervals according to the scale 0 and 4+. The only reaction was a $\pm$ reaction observed in one of the patients. Reactions were not observed in any of the normal subjects. No reactions were observed at control sites that had been treated with oleyl alcohol. The authors concluded that Jojoba alcohol was not phototoxic.[23]

Photoallergenicity

The photoallergenicity of a lip balm product containing 20.0% Jojoba Oil was evaluated using 30 subjects. For half of the subjects, approximately 0.2 g of the product was applied for 24 h to the inner aspect of the left arm, and for the remaining half, to the inner aspect of the right arm. Likewise, sites on the inner aspect of the right or left arm served as control (nonirradiated) sites. Each application was made via an occlusive patch on Mondays, Wednesdays, and Thursdays for a total of nine induction applications. If irritation was not

observed, all applications were made to the same site. After patch removal, each site was subjected to non-erythemogenic ultraviolet radiation for 15 min at a distance of 10 cm from the source. The dosage of UVA light was approximately 4,400 $\mu W/cm^2$. Each nonirradiated control site was covered during irradiation of the opposite arm. Irradiated sites were scored immediately after patch removal and 24 h after UV light exposure (72 h after irradiation on Friday) according to the scale: 0 (no evidence of any effect) to 4 (deep red erythema with vesiculation or weeping). After a 13-18 day nontreatment period, a challenge patch was applied for 48 h to a new site, and reactions were scored after patch removal. The test site was then irradiated and scored 24 h later. No reactions were observed, and the product was classified as nonphotoallergenic.[37]

SUMMARY

Jojoba Oil is defined as the oil expressed or extracted from seeds of the desert shrub, Jojoba *(Simmondsia chinensis).* It is used in cosmetic products at concentrations ranging from ≤ 0.1% to 25.0%.

Only a small fraction of the [^{14}C]Jojoba Wax (semisolid fraction of Jojoba Oil) injected subcutaneously into male albino mice was absorbed. The radioactivity TLC profile of carcass lipids indicated that approximately 90% of the ^{14}C remained in the lipid form in which it had been injected. The remaining ^{14}C was incorporated mainly into neutral lipids, such as triglycerides and fatty acids.

Fewer than 50% of the male albino rats that received an oral dose of Jojobl Oil (21.5 mg/kg) died. In another study, a lip balm product containing 20.0% Jojoba Oil was also nontoxic in Sprague-Dawley rats that received single oral doses of 5.0 g/kg. Results from short-term oral toxicity studies of Jojoba Oil (crude and refined) indicated no treatment-related effects.

No mortalities were reported in two groups of white rats that received single oral doses (5.0 g/kg) of a Jojoba ester. In a similar study, Jojoba Wax (5.0 g/kg) was also nontoxic in albino rats.

In an acute oral toxicity study on Jojoba alcohol involving three groups of mice of the dd Y-S strain, none of the doses of Jojoba alcohol, 32, 40, or 50 ml/kg, caused death.

No lesions were observed on the skins of mice that received repeated applications or subcutaneous injections of Jojoba Wax. The same was true for other organs examined.

Slight conjunctival hyperemia was observed in the eyes of rabbits 1 h after the instillation of Jojoba Oil. Reactions had cleared by 24 h post-instillation. However, a lip balm product containing 20.0% Jojoba Oil did not cause ocular irritation when instilled into the eyes of rabbits.

In two ocular irritation studies on Jojoba esters, one of the esters (iodine value = 60) caused conjunctival redness in one of six albino rabbits and the other ester (iodine value = 40) caused conjunctival redness in four of six albino rabbits. In a similar study on Jojoba Wax, conjunctival reactions were observed in three of six albino rabbits.

The ocular irritation potential of 12.5, 25.0, and 50.0% Jojoba alcohol (in refined Jojoba Oil) was evaluated using three groups of three rabbits, respectively. Conjunctival reactions were observed in all groups.

No significant skin irritation reactions were observed in albino guinea pigs patch tested with refined Jojoba Oil. In other skin irritation studies (patch tests) involving New Zealand white rabbits, a lip balm product containing 20.0% Jojoba Oil was considered minimally irritating, and an isomorphous mixture of partially isomerized Jojoba Oil, Jojoba Oil, and hydrogenated Jojoba Wax was, at most, a mild skin irritant.

The skin irritation (abraded and intact skin) potential of two Jojoba esters was evaluated using two groups of six albino rabbits, respectively. Positive skin irritation reactions were not observed in any of the animals patch tested. Similar negative results were reported in a skin irritation study on Jojoba Wax involving six albino rabbits.

In a skin irritation study using Jojoba alcohol, 10 white male rabbits were simultaneously patch tested with test substance concentrations of 12.5, 25.0, and 50.0% (in refined Jojoba Oil). The reactions observed were not different from those observed with the control, oleyl alcohol (l2.5, 25.0, and 50.0% concentrations). In the Draize test, no reactions were observed in 20 male and female albino marmots patch tested with 10.0% Jojoba alcohol (in refined Jojoba Oil).

In the maximization test, no sensitization reactions were observed in 20 male and female albino marmots patch tested with 10.0% Jojoba alcohol in refined Jojoba Oil.

An isomorphic mixture of *trans*-isomerized Jojoba Oil and hydrogenated Jojoba Wax was not mutagenic to strains TA97, TA98, TA100, and TA102 of *S. typhimurium* with and without metabolic activation. Jojoba alcohol also was found to be nonmutagenic to strains TA98, TA100, TA1535, TA1537, and TA1538 of *S. typhimurium* and *E. coli* strain WP-2 (*uvr* A) with or without metabolic activation.

A low incidence of skin irritation was observed in groups of patients, with histories of eczema or dermatitis, patch tested with Jojoba Oil (refined and crude).

In other studies, a topical oil product containing 0.5% Jojoba Oil and a lip balm product containing 20.0% Jojoba Oil were classified as nonirritants and nonsensitizers. Additionally, five of six subjects who were suspected of being sensitive to Jojoba Oil had positive reactions when patch tested with Jojoba Oil-olive oil and Jojoba Oil-petrolatum mixtures. However, sensitization reactions to pure Jojoba Oil were not observed in a control group of 28 patients with no known sensitivities.

Jojoba alcohol was not a skin irritant in 20 healthy subjects patch tested with concentrations of 10.0% and 100.0% and in 40 contact dermatitis patients patch tested with l00.0% Jojoba alcohol. Jojoba alcohol (10.0% and 100.0%) also was not phototoxic in any of the subjects tested.

In a two-day outdoor use test, a sunscreen oil containing 0.5% Jojoba Oil was not phototoxic in any of the subjects tested. A lip balm product containing 20.0% Jojoba Oil was neither phototoxic nor photoallergenic in studies in which subjects were irradiated with UVA light.

CONCLUSION

On the basis of the available animal and clinical data presented in this report, the CIR Expert Panel concludes that Jojoba Oil and Jojoba Wax are safe as cosmetic ingredients in the present practices of use and concentration.

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