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Final Report on the Safety Assessment of Sweet Almond Oil and Almond Meal

Sweet Almond Oil is used as an emollient and emulsifier in cosmetic products. Almond Meal is used as a skin cleanser and in medicated soaps.

Pharmacological studies reveal that Sweet Almond Oil is absorbed slowly through intact skin, whereas it is easily absorbed and digested following oral administration. It is nontoxic when ingested, and products containing up to 25% Sweet Almond Oil are practically nonirritating to rabbit skin and only minimally irritating to rabbit eyes. In subchronic studies, Sweet Almond Oil at 100% concentrations was only slightly irritating to rabbit skin.

In clinical studies, undiluted Sweet Almond Oil and products containing up to 25% Sweet Almond were practically nonirritating and nonsensitizing. Formulations containing up to 2% Sweet Almond Meal were practically nonirritating and nonsensitizing when tested in a repeated insult patch test.

On the basis of the available data and clinical experience, it is concluded that Sweet Almond Oil and Almond Meal are safe for topical application to humans in the present practices of use and concentration.

CHEMISTRY

Composition and Preparation

Sweet Almond Oil

Sweet Almond Oil is the fixed oil obtained from the ripe seed kernels of various species of *Prunus*. Almond kernels contain as much as 50% oil, which can either be physically expressed (35% yield) or chemically extracted (50% yield).[1]

Sweet Almond Oil consists mostly of triglycerides of oleic and linoleic acids. Other fatty acid glycerides are also present.[2] Table 1 summarizes the fatty acid composition of Sweet Almond Oil. Trace quantities of other fatty acids, vitamins (including vitamins A, B complex, and E), and amino acids (especially glutamic acid, aspartic acid, and arginine) have been identified as components of this ingredient.[3-5]

Almond Meal

Almond Meal is the solid residue remaining after the expression of oil from the ripe seed kernels of the species *Prunus amygdalus* or *P. communis*. The resi-

TABLE 1. Concentrations of Various Fatty Acids in Sweet Almond Oil.[a]

Fatty acid	*C chain length: Double bond(s)*	*Concentration range (%)*
Oleic	18:1	66.3–72.4
Linoleic	18:2	18.4–22.3
Palmitic	16:0	5.7–7.9
Stearic	18:0	0.5–1.2
Palmitoleic	16:1	0.4–0.7

[a]Data from Refs. 6–8.

due cake is then dried and ground to a controlled particle size. Almond Meal consists of proteins, carbohydrates, fat, fiber, sugar, ash, and up to 10% water.[2]

Properties

Sweet Almond Oil

Sweet Almond Oil is a pale, straw-colored or colorless liquid with a faint odor and mild taste. It is slightly soluble in alcohol, miscible with benzene, chloroform, and ether, and insoluble in water.[9] Table 2 lists other physical and chemical properties of Sweet Almond Oil.

Almond Meal

Almond Meal is a yellow to light-tan loose powder with an odor of fresh, ground almonds.[10]

TABLE 2. Chemical and Physical Properties of Sweet Almond Oil.

Property	*Value*	*Ref.*
Specific gravity	0.910,	11
	0.9311	12
Refractive index (20°)	1.541–1.546,	12
	1.4639,	1
	1.4626	8
Congealing temperature	−20°C	9
Acetyl value[a]	4.67	1
Reicher–Meissl number[b]	0.08	1
Saponification number	188	8
Iodine number	95–105	11
Peroxide number	0.61,	1
	0.00	8
Free fatty acid	0.027	8
Unsaponifiable material	0.53%	8
Unsaturated/saturated ratio	11.3	6

[a]Measures free OH groups.
[b]Measures volatile, soluble fatty acid content.

Reactivity/Stability

Sweet Almond Oil will undergo oxidation and other reactions typical of fixed oils. Autoxidation of this ingredient results in a decreased peroxide value, an increased acid value, and rancidity. The rate of autoxidation of Sweet Almond Oil increases as temperature increases. Marked changes in peroxide and acid values occurred when Sweet Almond Oil was either autoclaved at 122°C for 30 minutes and stored at 37.5°C, or stored at room temperature (20°–28°C) for ten weeks. The addition of antioxidants, such as propyl gallate, greatly increases the stability and shelf-life of Sweet Almond Oil.[13] Kedvessy[14] reported that almond oil tends to become rancid more quickly than other fixed oils.

Analytical Methods

Chromatography is frequently used to determine the presence or composition of Sweet Almond Oil. A common technique for determining the composition of Sweet Almond Oil involves saponification, esterification of the fatty acids to their methyl ester derivatives, and identification by gas chromatography.[6,7] The following is a list of other analytical methods used to identify this ingredient:

Gas chromatography[5,15]
Gas chromatography plus ultraviolet spectroscopy[16]
Thin-layer chromatography[3,5,15]
Vapor-phase chromatography plus infrared spectroscopy[17]
Spectrofluorimetry[3]
Iodochlorometric titration[18]

Almond Meal can be identified by infrared spectroscopy.[19]

USE

Cosmetic

The use of almond derivatives began with the ancient Hindus, who employed a paste made of crushed almonds as a body cleanser. In cosmetics today, almond products are widely used. Sweet Almond Oil, in shampoos, imparts a desirable sheen to the hair and acts as an oil/water emulsifier. As an emollient in skin care products, this ingredient is mildly occlusive and produces hydration, softening, and increased flexibility of the stratum corneum.[20] Almond Meal is used as a cleanser by people whose skin cannot tolerate soaps; it is also used in medicated soaps for the treatment of acne.[21,22]

According to the industry's voluntary submissions to the Food and Drug Administration (FDA) in 1976 (Table 3), Sweet Almond Oil is used in over 280 cosmetic formulations in concentrations up to 50%; lipsticks containing up to 25% Sweet Almond Oil comprise nearly two-thirds of these formulations. Almond Meal is reportedly used in 16 formulations at concentrations up to 25%.

The cosmetic product formulation computer printout which is made available by FDA is compiled through voluntary filing of such data in accordance with Title 21 part 720.4 of the Code of Federal Regulations.[25] Ingredients are listed in

TABLE 3. Product Formulation Data.[a]

Product category[b]	Total no. containing ingredient	No. product formulations within each concentration range (%)[b]						
		Unreported Concentration	>25–50	>10–25	>5–10	>1–5	>0.1–1	≤0.1
Sweet Almond Oil								
Bath oils, tablets, and salts	1	–	–	–	–	–	1	–
Fragrance preparations	3	–	–	–	–	3	–	–
Hair shampoo (noncoloring)	1	–	–	–	–	–	–	1
Blushers (all types)	3	–	–	–	3	–	–	–
Face powders	1	–	–	–	–	–	–	1
Makeup foundations	2	–	–	–	1	–	1	–
Lipstick	184	–	–	65	96	7	14	2
Makeup bases	5	–	–	–	–	2	3	–
Nail polish and enamel removers	1	–	–	–	–	–	–	1
Shaving cream (aerosol, brushless, and lather)	1	–	–	–	–	1	–	–
Skin cleansing preparations (cold creams, lotions, liquids, and pads)	12	–	1	1	2	5	2	1
Face, body, and hand skin care preparations (excluding shaving preparations)	9	–	–	–	–	9	–	–
Moisturizing skin care preparations	21	–	–	2	2	11	5	1
Night skin care preparations	17	–	1	2	3	11	–	–
Paste masks (mud packs)	3	–	–	–	–	3	–	–
Other skin care preparations	6	–	–	1	1	3	1	–
Suntan gels, creams, and liquids	10	–	–	1	1	6	2	–
1976 TOTALS	280	–	2	72	109	61	29	7
1979 TOTALS[c]	114	–	1	6	20	61	20	60
Almond Meal								
Skin cleansing preparations (cold creams, lotions, liquids, and pads)	6	–	–	1	1	4	–	–
Paste masks (mud packs)	6	–	–	–	–	5	1	–
Other skin care preparations	4	–	–	–	–	2	2	–
1976 TOTALS	16	–	–	1	1	11	3	–
1979 TOTALS[c]	15	–	–	–	1	11	3	–

[a]Data from Ref. 23.

[b]Preset product categories and concentration ranges in accordance with federal filing regulations (21 CFR 720.4).

[c]Data from Ref. 24.

prescribed concentration ranges under specific product type categories. Since certain cosmetic ingredients are supplied by the manufacturer at less than 100% concentration, the value reported by the cosmetic formulator may not necessarily reflect the true, effective concentration found in the finished product; the effective concentration in such a case would be a fraction of that reported to the FDA. The fact that data are only submitted within the framework of preset concentration ranges also provides 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 tenfold error in the assumed ingredient concentration.

Products containing Sweet Almond Oil or Almond Meal contact the lips, face, nails, skin, and hair. Such products are used daily or occasionally; contact with these ingredients could be continuous.

Pharmaceutical

As a pharmaceutical aid, Sweet Almond Oil is used as an emollient and perfume.[9] Sweet Almond Oil has also been used as a solvent for parenterally administered drugs.[13] In Britain, it is used as a solvent in injectable solutions for hemorrhoid treatment.[26,27]

BIOLOGICAL PROPERTIES

Antibacterial Effects

In an early antimicrobial study of natural oils, Sweet Almond Oil was added to cultures of bacteria; numbers of viable organisms were counted at various intervals following treatment. After five hours, Sweet Almond Oil reduced the number of viable bacteria by 98.9%.[28] In another test, the bacteriocidal activity of various natural oils on *Staphylococcus aureus* was studied. Oils were added to bacterial cultures, and the time required to reduce the number of viable organisms to zero was measured. Sweet Almond Oil required 3–4 days; this value was much higher than the other oils tested, indicating lower activity.[29]

Absorption, Metabolism, and Excretion

The percutaneous absorption of Sweet Almond Oil was studied in adult albino rats. A solution containing this ingredient and physostigmine was applied to the skin of each animal; latency time to muscle contraction was then measured. When compared to other oil mixtures tested, Sweet Almond Oil-physostigmine had a relatively long latency time, indicating lower percutaneous absorption. The authors concluded that increased amounts of short chain and polyunsaturated fatty acids in oils favor their percutaneous absorption.[30]

When ingested, di- and triglycerides are hydrolyzed to monoglycerides by lipases. In the duodenum, the monoglycerides form mixed micelles with the free fatty acids, bile salts, cholesterol, and sodium ions. The micelle then penetrates the mucosal cell brush border where the free fatty acids and monoglycerides are

resynthesized to triglycerides in the endoplasmic reticulum. Proteins and phospholipids, synthesized in the mucosal cell, combine with cholesterol to produce a specific lipoprotein, which coats the triglyceride, forming a chylomicron. The chylomicra then leave the intestinal mucosal cell and enter the lymphatic system and the blood. Capillary endothelial cell-bound lipoprotein lipases degrade the chylomicra, freeing the fatty acids and glycerol for cellular uptake and subsequent lipid storage or catabolism.[31,32]

Deuel and Holmes[33] studied the digestability of natural oils in humans. Two men were placed on a three-day, fat-free, basal diet which included a cornstarch pudding containing a test oil. Sweet Almond Oil was well-digested (97%) when compared to other oils. In another study, Sweet Almond Oil or whole almonds were added to a lipid-free basal diet at concentrations of 10% and 18%, respectively, and fed to groups of three rats for three days. Absorption of the Almond Oil was 98%–99% complete.[34]

The digestion of several edible vegetable oils was studied enzymatically, in vitro. At room temperature, Sweet Almond Oil was degraded slowly by pancreatic lipase when compared to other oils tested.[35] A comparatively slow rate of digestion by pancreatic lipase was also observed in an experiment performed at 37°C.[36]

Animal Toxicology

Acute Studies

Oral Toxicity

Undiluted Sweet Almond Oil and products containing 2%–18% Sweet Almond Oil were tested for acute oral toxicity. Test materials were administered to groups of five to ten animals, at one or more dose levels. Animals were then observed for 5–14 days for signs of toxicity, as well as changes in appearance or behavior. In some studies, animals were sacrificed and necropsied at the end of the observation period. Results of these tests indicate that undiluted Sweet Almond Oil and products containing up to 18% Sweet Almond Oil are practically nontoxic (Table 4).

A soap containing 2% Almond Meal was tested for acute oral toxicity. The test material was administered to a group of five rats at a dose of 5 g/kg. Animals were observed for up to 14 days for signs of toxicity, as well as changes in appearance or behavior. Results of this test, summarized in Table 4, indicate that the soap containing 2% Almond Meal was practically nontoxic.[37]

Dermal Toxicity

Undiluted Sweet Almond Oil was tested for acute dermal toxicity in guinea pigs. The test material was applied under occlusion to the clipped abraded and intact skin of 12 animals (6 M/6 F) at a dose of 3 g/kg. At 24 hours, excess material was rinsed off. Observations were made daily for seven days; animals were then sacrificed and necropsied. The acute dermal LD50 was >3 g/kg, indicating that Sweet Almond Oil is practically nontoxic by percutaneous absorption.[38]

TABLE 4. Acute Oral Toxicity.

Ingredient (product)	*Effective conc. (%)*	*Dose (g/kg)*	*No. and spec. of animal*	*LD50 (g/kg)*	*Comment*[a]	*Ref.*
Sweet Almond Oil	Undiluted	5	5 rats	>5	Practically nontoxic	38
Sweet Almont Oil	Undiluted	up to 14.7	5–10 rats/group	>14.7	Practically nontoxic	39
Sweet Almond Oil (18% in a moisturizer)	9	up to 15.9	5–10 rats/group	–[b]	Moisturizer was relatively harmless	40
Sweet Almond Oil (2.5% in a foundation)	2.5	up to 15.9	5–10 rats/group	–	Foundation was relatively harmless	41
Sweet Almond Oil (2% in a moisturizer)	2	10	10 mice	–	Moisturizer was practically nontoxic	42
Almond Meal (2% in a soap)	2	5	5 rats	–	Soap was practically nontoxic	37

[a]According to Hodge and Sterner, Ref. 43.
[b]The LD50 value for this product was not reached at the highest dose tested.

Subcutaneous Toxicity

Guinea pigs were injected subcutaneously with single or multiple doses of a 10% Sweet Almond Oil emulsion in saline (1 ml/dose). After a single injection, minute oil emboli were found in the lungs of these animals. After six to ten hours, emboli caused local infiltration of eosinophils in the lung parenchyma. Six days after repeated oil injections, investigators observed a peripheral blood eosinophilia, which reached a maximum increase of 16.5% by the third week. The eosinophilia was suggested to be a nonallergic reaction.[44]

Primary Skin Irritation

Undiluted Sweet Almond Oil was tested for irritancy in groups of six male albino rabbits. The test material was applied under occlusion to the clipped intact and abraded dorsal skin of each animal. Twenty-three hours later, patches were removed; sites were scored at 24 and 48 hours. The Primary Irritation Indices (PIIs) for seven test samples of Sweet Almond Oil ranged from 0 to 0.18 (maximum score = 8), indicating that this ingredient is practically nonirritating to skin.[45] Table 5 summarizes primary skin irritation data.

Undiluted Sweet Almond Oil and two formulations each containing 25% Sweet Almond Oil were tested for skin irritancy by the following procedure. The test material was applied under occlusion to the shaved intact dorsal skin of groups of nine female albino rabbits. Patches were removed and sites were scored for erythema at 24 and 72 hours. Undiluted Sweet Almond Oil was nonirritating (PII = 0; maximum score = 4); whereas, the formulations containing 25% Sweet Almond Oil were minimally irritating (PIIs = 0.28 and 0.72, respectively). Results are presented in Table 5.

Almond Meal, undiluted and in aqueous slurry, was tested for skin irritation in rabbits (Table 5). The test material was applied under occlusion to the shaved

TABLE 5. Primary Skin Irritation.

Ingredient (product)	*Effective conc. (%)*	*No. of rabbits*	Skin: *intact(i) abraded(a)*	Results *PII*[a]	Results *PSI*[b]	*Comment*	*Ref.*
Sweet Almond Oil	Undiluted	6	i,a	0.04		Practically nonirritating	45
	Undiluted	6	i,a	0.00		Nonirritating	45
	Undiluted	6	i,a	0.00		Nonirritating	45
	Undiluted	6	i,a	0.18		Practically nonirritating	45
	Undiluted	6	i,a	0.00		Nonirritating	45
	Undiluted	6	i,a	0.04		Practically nonirritating	45
	Undiluted	9	i		0.00	Nonirritating	38
Sweet Almond Oil (25% in a moisturizer)	25	9	i		0.28	Practically nonirritating	46
	25	9	i		0.72	Practically nonirritating	47
Almond Meal	Undiluted	9	i		0.27	Practically nonirritating	48
	Aqueous slurry	9	i		0.20	Practically nonirritating	10

[a]Primary Irritation Index – maximum value = 8.0.
[b]Primary Skin Irritation – maximum score = 4.0 (erythema only).

intact dorsal skin of groups of nine female albino rabbits. Patches were removed and sites were scored for erythema at 24 and 72 hours. Almond Meal, undiluted and in aqueous slurry, was minimally irritating (PIIs = 0.27 and 0.20, respectively; maximum score = 4).[10,48]

Primary Eye Irritation

The Draize method or a modification of it was used to test the eye irritancy of undiluted Sweet Almond Oil and cosmetic formulations containing up to 25% Sweet Almond Oil. The test material was instilled into one eye of each of three to six rabbits; the other eye served as an untreated control. Irritation was evaluated one hour, as well as one, two, three, four, and seven days later. Undiluted Sweet Almond Oil was practically nonirritating or minimally irritating. Formulations containing up to 25% Sweet Almond Oil were nonirritating to minimally irritating. In most instances, reactions that occurred were limited to conjunctival irritation, which cleared by the third day of observation (Table 6).

Undiluted Almond Meal and a soap containing 8% Almond Meal were tested for primary eye irritation in groups of six rabbits. The test material was instilled into one eye of each animal; the other eye served as an untreated control. Irritation was evaluated as above. Results of these tests, summarized in Table 6, indicate that undiluted Almond Meal was practically nonirritating; whereas, the soap containing 8% Almond Meal was minimally irritating.[10,37]

Subchronic Studies

Dermal Toxicity

A medicated soap containing 2% Almond Meal was tested for dermal toxicity in a 12-week rabbit study. A solution of the soap containing 0.5% Almond Meal

TABLE 6. Primary Eye Irritation.

Ingredient (product)	Effective conc. (%)	No. of rabbits	Draize eye irritation score[a] 1 Hr.	Day 1	2	3	4	7	AOII[b]	Comment[c]	Ref.
Sweet Almond Oil	Undiluted	6							8.17	Minimally irritating	45
Sweet Almond Oil	Undiluted	6							5.00	Minimally irritating	45
Sweet Almond Oil	Undiluted	6							6.50	Minimally irritating	45
Sweet Almond Oil	Undiluted	6							3.83	Minimally irritating	45
Sweet Almond Oil	Undiluted	6							4.00	Minimally irritating	45
Sweet Almond Oil	Undiluted	6							7.00	Minimally irritating	45
Sweet Almond Oil	Undiluted	6							3.50	Minimally irritating	45
Sweet Almond Oil	Undiluted	6		1	0	0	0	0		Practically nonirritating	38
Sweet Almond Oil	Undiluted	3		2	0	0	0	0		Practically nonirritating	39
Sweet Almond Oil (25% in a moisturizer)	25	6		1	0	0	0	0		Practically nonirritating	46
Sweet Almond Oil (25% in a moisturizer)	25	6		1	0	0	0	0		Practically nonirritating	47
Sweet Almond Oil (18% in a moisturizer)	9	3	4	0	0	0	0	0		Minimally irritating	40
Sweet Almond Oil (25% in a makeup)	2.5	3	4	2	0	0	0	0		Minimally irritating	41
Sweet Almond Oil (20% in a moisturizer)	2.0	3		0	0	0	0	0		Nonirritating	50
Almond Meal	Undiluted	6		1	1	1	0	0		Practically nonirritating	10
Almond Meal (8% in a soap)	0.16	6		9	1	0	0	0		Minimally irritating	37

[a]Maximum score = 110.
[b]Acute Ocular Irritation Index (maximum score = 110).
[c]According to Draize.

was applied daily, five days per week, to the clipped intact skin of 14 animals at a dose of 199 mg/kg (4 mg/kg Almond Meal). The solution was washed off one hour after application. Animals were observed daily for changes in weight, general appearance, and behavior. Skin sites were graded daily for irritation. Blood and urine were analyzed before, during, and after treatment. Animals were sacrificed and necropsied after 12 weeks. During the course of the experiment, six of the animals died or had to be sacrificed owing to an outbreak of Pasteurellosis. The disease complicated identification of systemic treatment-related effects. Dermatopathological examination of treated skin revealed a moderate inflammatory dermal response. Slight to moderate erythema, cracking, and desquamation, which are clinical indications of irritancy, were observed. No other treatment-

related effects were observed. The investigators suggested that the reactions were typical of exaggerated exposure to such products and would not be expected to occur in humans under normal conditions of use.[49]

Skin Irritation

A 60-day cumulative irritation test was used to evaluate the subchronic irritancy of Sweet Almond Oil in rabbits. The test material, at concentrations of 10% or 100%, was applied daily to the clipped dorsal skin of groups of three albino rabbits. Sites were scored daily. When tested in seven separate trials, 100% Sweet Almond Oil produced mean maximum irritation indices (MMIIs) ranging from 0.34 to 1.34 (maximum score = 8). At a concentration of 10%, MMIIs for this ingredient ranged from 0 to 0.66. Results indicated that, when applied to the skin over a long period of time, undiluted Sweet Almond Oil is slightly irritating; whereas, at 10% it is practically nonirritating.[45]

Sensitization

The Magnusson–Kligman Maximization Assay was used to determine the sensitizing potential of Sweet Almond Oil. Hartley-strain female guinea pigs were divided into groups of ten animals. Each animal received intradermal injections of 50% aqueous Freund's Complete Adjuvant (FCA), 5% Sweet Almond Oil in propylene glycol, and 5% Sweet Almond Oil in 50% FCA into different sites on epilated dorsal skin. Vehicle control animals were also used. In the dose-range phase of the experiment, each of 50 animals received a single dermal application of 5%, 10%, or 100% Sweet Almond Oil to determine "subirritating" and "slightly irritating" concentrations to be used for the challenge and booster phases. One week after the induction injection, 100% Sweet Almond Oil was applied occlusively to the treated sites for 48 hours as a topical booster. Animals were challenged two weeks later with 5% Sweet Almond Oil in petrolatum applied topically under occlusion for 24 hours. Patches were then removed and sites were scored 24 and 48 hours later. Sweet Almond Oil was nonsensitizing under these test procedures.[51]

Clinical Assessment of Safety

Irritation and Sensitization

A single insult patch test (SIPT) was used to determine the irritancy of undiluted Sweet Almond Oil. The test material was applied under occlusion to the backs of 101 subjects; 48 hours later, the patches were removed and the sites scored. Sweet Almond Oil produced no reactions in the test subjects and was determined to be nonirritating.[39]

A repeated insult patch test (RIPT) was used to study the irritancy and sensitizing potential of undiluted Sweet Almond Oil in 52 subjects. The test material was applied under occlusion to the back of each subject for 48 hours; sites were then read and the compound reapplied. This procedure was repeated three days per week for three weeks (nine applications). Following a two-week rest, one or two challenge patches were applied to previously untreated skin of each subject. Sites were scored 48 and/or 96 hours later. Undiluted Sweet Almond Oil pro-

duced no reactions in any of the 52 subjects and was concluded to be nonirritating and nonsensitizing.[39]

A repeated insult patch test was used to study the effects of cosmetic formulations containing 0.1%–25% Sweet Almond Oil in a total of 6906 subjects. Results indicate that these products are practically nonirritating and nonsensitizing to human skin (Table 7). Additionally, the Lanman-Maibach 21-day Cumulative Irritancy Assay was used to test the subchronic irritancy of a moisturizer containing 25% Sweet Almond Oil. The test material was applied under occlusion to the backs of ten subjects for 23 hours. Patches were then removed, the site rinsed and scored one hour later, and the compound reapplied. This procedure was repeated for 21 consecutive days. Of the ten subjects tested, seven reacted to one or more patches. The total irritancy score was 14 out of a maximum possible 630.[52]

TABLE 7. Clinical Assessment.

Ingredient (product)	*Effective conc. (%)*	*Test*	*No. of subjects*	*Result*	*Comment*	*Ref.*
Sweet Almond Oil	100	SIPT[a]	101	0/101	Nonirritating	39
Sweet Almond Oil	100	RIPT[b]	52	0/52	Nonirritating and nonsensitizing	39
Sweet Almond Oil (25% in a moisturizer)	25	SIPT	20	PII = 0.10[c]	Practically nonirritating	56
Sweet Almond Oil (18% in a moisturizer)	18	RIPT	98	0/98	Nonirritating and nonsensitizing	57
Sweet Almond Oil (2.5% in a foundation)	2.5	SIPT	100	0/100	Nonirritating	40
Sweet Almond Oil (2.5% in a foundation)	2.5	SIPT	100	0/100	Nonirritating	41
Sweet Almond Oil (2% in a moisturizer)	2.0	RIPT	104	1/104	Two subjects showed "doubtful reactions" during induction phase and one during the challenge phase	58
Sweet Almond Oil (0.1% in a face powder)	0.1	RIPT	148	0/148	Nonirritating and nonsensitizing	55
Sweet Almond Oil (0.2–2% in a suntan lotion)	0.2–2.0	RIPT	6336	0/6336	Nonirritating and nonsensitizing	55
Almond Meal (2% in a medicated soap)	0.01	SIPT	19	PII = 0.05[c] 1/19	Practically nonirritating	53
Almond Meal (2% in a soap)	0.01	RIPT	86	0/86	Nonirritating and nonsensitizing	54

[a]Single insult patch test.
[b]Repeat insult patch test.
[c]Primary irritation index (maximum score = 4).

A single insult patch test and a repeated insult patch test were used to evaluate the irritancy and sensitizing potential of two soaps, each containing 2% Almond Meal, in 19 and 86 subjects, respectively (Table 7). The test compounds were applied and sites were evaluated as outlined above. In the SIPT, only 1 of the 19 subjects reacted to the soap; the PII was 0.05 (maximum score = 4), indicating that the soap containing 2% Almond Meal was practically nonirritating.[53] In the RIPT, there were no reactions in any subject to induction or challenge patches, indicating that this soap was nonirritating and nonsensitizing.[54]

A six-week acne study compared the irritancy and efficacy of two medicated soaps, one of which contained 2% Almond Meal. Preliminarily, each subject's skin was graded by a dermatologist with regard to numbers of open and closed comedones, pustules, and papules, as well as oiliness, scaling, and overall complexion. Parameters were scored on a scale of 0–6, except oiliness, which was evaluated as mild, moderate, or excessive. On the basis of these gradings, 100 subjects were divided into two equal groups; each group was instructed to use one of the two test soaps twice daily in lieu of their usual soaps. Subjects were reexamined after 2, 4, and 6 weeks of treatment. Statistically, both products produced significant skin improvement; the product containing Almond Meal was judged superior to the other soap in three test parameters (overall complexion, as well as the numbers of open and closed comedones). The investigator concluded that both products, when used as directed, are safe and effective in reducing manifestations of mild acne. Except for one subject in each test group, neither product induced significant irritation or sensitization.[22]

Photosensitivity

Formulations containing 0.1%–2.0% Sweet Almond Oil were tested for photosensitization in a total of 764 subjects. The test material was applied under occlusion to each subject's back. Twenty-four hours later, the patch was removed and the site scored and irradiated with ultraviolet light from a 150W Xenon Arc Solar Simulator (290–400 nm) at a dose equal to three times the individual's minimal erythema dose (MED). The site was again graded at 72 hours and the procedure repeated once. The products containing 0.1%–2.0% Sweet Almond Oil did not manifest photosensitivity in any of the test subjects.[55]

SUMMARY

Sweet Almond Oil and Almond Meal are natural products obtained from the ripe seed kernels of various species of *Prunus*. Approximately 50% of the kernel consists of Sweet Almond Oil; the residue left after oil expression is the source of Almond Meal. Sweet Almond Oil consists mostly of triglycerides of oleic and linoleic acids. Other fatty acids, diglycerides, vitamins, and amino acids are also found in this ingredient. Almond Meal consists of proteins, carbohydrates, fat, fiber, and water.

Sweet Almond Oil is used as an emollient in skin care products and as an emulsifier in hair products. Almond Meal is used as a skin cleanser by people

whose skin cannot tolerate soaps; it is also used in medicated soaps intended for people with acne. Sweet Almond Oil and Almond Meal are used in over 280 and 16 cosmetic formulations at concentrations up to 50% and 25%, respectively.

Pharmacological studies reveal that Sweet Almond Oil is absorbed slowly through intact skin, whereas it is easily and completely digested and absorbed upon oral administration. When ingested, the fatty acid glycerides of Sweet Almond Oil are hydrolyzed, micellized, converted to triglycerides, and packaged into chylomicra. These then enter the lymphatic system, ultimately ending up in the blood and transferred to cells, where the fatty acids are released enzymatically from the chylomicra for cellular catabolism or lipid storage.

Animal toxicity studies indicate that undiluted Sweet Almond Oil is practically nontoxic when ingested and when applied undiluted to the skin of guinea pigs. Undiluted Sweet Almond Oil and products containing up to 25% Sweet Almond Oil are practically nonirritating to rabbit skin and practically nonirritating or minimally irritating to rabbit eyes. In subchronic studies, Sweet Almond Oil at 10% and 100% concentrations was practically nonirritating and slightly irritating, respectively, to rabbit skin in a 60-day cumulative irritancy test. In addition, Sweet Almond Oil was nonsensitizing in a Magnusson–Kligman Maximization test.

A soap containing 2.0% Almond Meal was practically nontoxic when ingested by rats in an acute oral toxicity study. Undiluted Almond Meal was practically nonirritating to rabbit skin. Undiluted Almond Meal was practically nonirritating to rabbits' eyes, whereas a soap containing 0.5% Almond Meal was minimally irritating. In a 12-week subchronic dermal toxicity test in rabbits, a soap solution containing 0.5% Almond Meal was slightly to moderately irritating; no other treatment-related effects were observed.

In clinical studies, undiluted Sweet Almond Oil and products containing 0.1%–25% Sweet Almond Oil were practically nonirritating and nonsensitizing when tested in a total of 7059 subjects. Additionally, a moisturizer containing 25% Sweet Almond Oil was minimally irritating when applied for 21 consecutive days to the backs of ten subjects. Results of photo patch tests of formulations containing up to 2% Sweet Almond Oil in 764 subjects indicated that these products do not manifest photosensitization.

Soaps containing 2% Almond Meal were practically nonirritating and nonsensitizing when tested in a single insult patch test involving 19 subjects and a repeated insult patch test involving 86 subjects. Results of a six-week acnegenic study indicated that a medicated soap containing 2% Almond Meal was safe and effective, as well as practically nonirritating and nonsensitizing.

CONCLUSION

On the basis of the available animal data and limited clinical experience presented in this report, the Panel concludes that Sweet Almond Oil and Almond Meal are safe for topical application to humans in the present practices of use and concentration.

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