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Final Amended Report on the Safety Assessment of Mink Oil[1]

Mink Oil, obtained from the fatty tissues of minks, is a mixture of the natural glycerides of 14 to 20 carbon chain fatty acids. There are 100 current reported uses as a hair-conditioning agent, an occlusive skin-conditioning agent, and as a surfactant; up to a maximum concentration of 3%. Mink Oil is manufactured by harvesting animal hides and scraping the fat layer from the hide. It is rendered and refined using high temperature processes (230°F to 240°F) and saponification to reduce free fatty acids. Analyses demonstrate that Mink Oil can be substantially free of impurities, including pesticides. Mink Oil does not absorb significant UVA or UVB radiation. In a clinical test of skin penetration, 1 h after application, Mink Oil was detected on the skin surface of all five panelists; it was detected within the stratum corneum in 2/5 panelists. Mink Oil has an oral LD_{50} of >64.0 cc/kg in albino rats. No erythema or edema was noted after refined Mink Oil was applied for 24 h to intact and scarified area of albino rabbits. A 50% dilution of a Mink Oil cream did not sensitize guinea pigs in a maximization test. Mink Oil was not an ocular irritant to albino rabbits. Clinical studies using single occlusive patches found no irritation with up to 2.8% Mink Oil, although transient mild to no irritation was noted in two exaggerated-use studies. Mink Oil is used in aerosols and sprays. Although there are no inhalation toxicity data available on Mink Oil, the available data on particle sizes of cosmetic aerosols and sprays indicates diameters more than an order of magnitude larger than the diameter of respirable particles. Most of the glycerides in Mink Oil are triglycerides (glyceryl triesters), the safety of which has been substantiated in previous safety assessments; e.g., dermal absorption is nil to slight; there is little or no acute, subchronic, or chronic oral toxicity; dermal application was not associated with significant irritation or sensitization; ocular exposures were, at most, mildly irritating; most of the genotoxicity test systems are negative; use as vehicles in carcinogenicity testing of other chemicals has produced no adverse reaction; and clinical tests produce no irritation or sensitization reactions—but, they may enhance the of penetration of other chemicals. Formulators should be aware of the possible penetration-enhancing properties of Mink Oil. Although pesticide residues have been analyzed and found to be below levels of detection, the Panel is concerned that the available data suggesting the absence of pesticide residues in Mink Oil are limited. The Panel advised the industry that the total polychlorinated biphenyl (PCB)/pesticide contamination should be limited to not more than 40 ppm, with not more than 10 ppm for any specific residue.

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[1]Reviewed by the Cosmetic Ingredient Review Expert Panel.

INTRODUCTION

This amended safety assessment updates and supersedes an earlier Cosmetic Ingredient Review (CIR) safety assessment of Mink Oil (CIR 1995). New information is included on the manufacturing process; batch analysis data; pesticide residue analysis; updated concentration of use; and ultraviolet (UV) absorption spectra. Information provided by the Cosmetic, Toiletry, and Fragrance Association (CTFA) indicated that most glycerides in Mink Oil are triglycerides (CTFA 2001a). The safety of triglycerides in cosmetics was assessed by CIR, with the conclusion that these ingredients are safe as used in cosmetics (CIR 1999). In addition, CIR has published a safety assessment of Oleic, Lauric, Palmitic, Myristic, and Stearic Acids (Elder 1987). Uses of both the triglycerides group and fatty acid group of ingredients in cosmetics at maximum concentrations ranging from 25% to 50% were determined to be safe. On the basis of the available data the Panel issued this amended safety assessment.

CHEMISTRY

Method of Manufacture

Mink Oil is a mixture of the natural glycerides of 14 to 20 carbon chain fatty acids obtained from the subdermal fatty tissues of the mink (Pepe et al. 2002).

EMULAN, Inc. (1990) uses Northern Ranch Mink as the source for Mink Oil. Animals are raised in cages and kept free from disease and are harvested typically in late fall/early winter.

The fat is scraped from the hides of the mink and frozen until it is rendered and refined. The fat is rendered at temperatures ranging from 220°F to 240°F for a minimum of 5 h, after which the saturated fat is separated from the unsaturated fat using filtration. A saponification process then further separates the free fatty acids; i.e., the saponified free fatty acids form soap at the bottom. The oil is further bleached and clarified using diatomaceous earth, again at the high temperature described above. Impurities such as any remaining soap or any proteinaceous impurity (e.g., collagen) are removed at this stage (EMULAN, Inc. 1990; Complete Analysis Laboratories, Inc. 1996; CTFA 1999a).

Chemical Composition

According to the *Compendium of Cosmetic Ingredient Composition* (Nikitakis and McEwen 1990), the oil is a mixture of the natural glycerides of 14 to 20 carbon chain fatty acids; approximately 75% of the composition is 16 to 18 carbon chain

TABLE 1
Fatty acid composition of two Mink Oils (CTFA 1994)

Fatty acid	Carbon chain length/ number of unsaturated C:C bonds	Mink Wax Oil (as %)	Mink Crude Oil (as %)
Lauric	12/0	0.1	0.1
Myristic	14/0	4.0	3.5
Myristoleic	14/1	0.7	0.9
Pentadecanoic	15/0	0.2	0.1
Palmitic	16/0	28.0	17.2
Palmitic	16/1	13.3	17.0
Heptadecanoic	17/0	0.5	0.4
Heptadecanoic	17/1	0.6	0.5
Stearic	18/0	4.7	2.5
Oleic	18/1	35.3	40.9
Linoleic	18/2	10.6	15.0
Linolenic	18/3	0.4	0.6
Eicosanoic	20/0	0.1	—
Eicolenoic	20/1	0.7	0.6
Total fatty acid		99.2	99.3
Unsaturated		61.6	75.5
Saturated		37.6	23.8

fatty acid glycerides. The detailed fatty acid composition of two forms of Mink Oil (Mink Wax Oil and Mink Crude Oil) provided by one supplier is given in Table 1 (CTFA 1994).

Physical and Chemical Properties

Mink Oil is a pale yellow liquid with a mild characteristic odor. It is soluble in chloroform, carbon tetrachloride, ether, benzene, acetone, and isopropanol and is insoluble in water. The refractive index at 25°C is between 1.4665 and 1.4675. The freezing point is 5°C maximum; the saponification value is 190 to 220; the iodine value is 80 to 90 (Nikitakis and McEwen 1990). SGS Control Services Inc. (1994) reported a specific gravity of 0.91437 and a refractive index at 40°C of 1.4623. Jennings Laboratories, Inc. (1999) reported a specific gravity at 25°C of 0.9110 and a refractive index at 25°C of 1.4680. One supplier reported that because of its iodine value, Mink Oil "exhibits very low oxidation and degradation" (CTFA 1994).

UV Absorption

Mink Oil prepared according to the manufacturing process described above has significant absorbance only in the UVC region. Absorption maxima in a 0.5% sample occur at 212 nm (2.59700 absorption units), 270 nm (0.55858 absorption units), and a small absorption at 316 nm (0.07776 absorption units). A 0.05% solution had no detectable absorption at 316 nm (CTFA 1999b).

Impurities

One analysis reported 0.0628% moisture, 0.0012% unsaponifiable matter, and 0.0002% insolubles (Jennings Laboratories, Inc. 1999).

Analysis of one sample of Mink Oil found no detectable levels of the following tradename polychlorinated biphenyls (PCBs): Arochlor 1016, 1221, 1232, 1242, 1248, 1254, and 1260. The assay had a minimum detection limit of 0.5 μg/L (New Jersey Laboratories/A.A. Labs Division 1995).

Pesticide analyses of two samples produced the results shown in Table 2. No explanation was provided for the different detection limits for the two sample analyses, although it was reported that they were done at different times (CTFA 2001a).

The United States Pharmacopeia (USP) standards for lanolin, for comparison purposes, limit PCB/pesticide contamination to not more than 40 ppm, with not more than 10 ppm for any specific residue (U.S. Pharmacopeia 1995).

COSMETIC USE

Mink Oil is used in formulations as a hair conditioning agent, an occlusive skin conditioning agent, and a surfactant (Pepe et al. 2002). Based on information received from industry, the Food and Drug Administration (FDA) lists 100 current uses of Mink Oil (FDA 2001). The uses of Mink Oil as a function of product type are given in Table 3. The product types and the total number of each product type reported to FDA (FDA 2001) are given, with the number of formulations of that product type that were reported to contain Mink Oil; e.g., of 187 mascara products, only one contains Mink Oil. Current concentration of use data provided by industry (CTFA 1999c, 2001b) as a function of product type are also included in Table 3. These data indicate that Mink Oil is reportedly used in a given product category, but the concentration of use is not available. In other cases, information regarding use concentration for specific product categories is provided, but the number of such products is not known.

Mink Oil is used in products that are or may be found in sprays or aerosols. Cosmetic product sprays and aerosols produce large particle sizes. For example, aerosol hair sprays have particles of 60 to 80 μ diameter, with $<1\%$ below 10 μ, and pump hair sprays have particle diameters of ≥ 80 μ (Bower 1999). These particle sizes are larger than the mean aerodynamic diameter of respirable particles, which is 4.25 ± 1.5 μ (Jensen and O'Brien 1993).

The European Commission (EC) has not included Mink Oil in the list of substances which cosmetic products must not contain or must not contain except subject to restrictions and conditions laid down (EC 2002). In the current Japanese Ministry of Health, Labor and Welfare (MHLW) regulations, Mink Oil is not included on a negative list (MHLW 2000a), on a list of ingredients for which there are restrictions to use in cosmetics (MHLW 2000b), or on a list of quasi-drugs for which listing is required (MHLW 2000c).

TABLE 2
Pesticide residues in Mink Oil (CTFA 2001b)

	8/7/96 sample		10/7/96 sample	
Pesticide	Level in Mink Oil (mg/kg)	Min. detectable level (mg/kg)	Level in Mink Oil (mg/kg)	Min. detectable level (mg/kg)
A-BHC	U*	0.020	U	0.020
B-Bhc	U	0.020	U	0.020
G-BHC (Lindane)	U	0.020	0.11	0.020
D-BHC	U	0.020	U	0.020
Heptachlor	U	0.020	U	0.020
Aldrin	U	0.020	U	0.020
Heptachlor Epoxide	U	0.020	U	0.020
Endosulfan I	U	0.020	U	0.020
A-Chlordane	U	0.020	U	0.020
G-Chlordane	U	0.020	U	0.020
Dieldrin	U	0.020	U	0.020
4,4′-DDE	0.27	0.020	U	0.020
Endrin	U	0.020	U	0.020
Endosulfan II	U	0.020	U	0.040
4,4′-DDD	U	0.020	U	0.040
Endrin Aldehyde	U	0.020	U	0.040
Endosulfan Sulfate	U	0.020	U	0.040
4,4′-DDT	U	0.020	U	0.040
Endrin Ketone	U	0.020	U	0.040
Methoxychlor	U	0.020	U	0.020
Toxaphene	U	0.020	U	1.00

*U = undetectable.

ABSORPTION, DISTRIBUTION, METABOLISM, AND EXCRETION

Absorption

Xienta Institute for Skin Research (1988) conducted an attenuated total reflectance–infrared spectroscopy study (ATR-IR) to determine the penetration of a commercial preparation of Mink Oil into human stratum corneum. Five healthy Caucasian females were instructed to refrain from applying any topical agents to their forearms 24 h prior to the study. A site on one forearm of each panelist was treated with 50 μl of the test substance. The same site on the other forearm was not treated and served as control. Both sites were scanned prior to product application. Scanning consisted of placing the subject's forearm directly onto a germanium plate and conducting an IR spectra for wavelengths between 800 and 4000 cm^{-1}. The germanium plate served as an internal reflection crystal. One hour after application, the sites were again scanned. This was followed by tape stripping and scans after 5, 10, and 15 tape strippings. The same scans were conducted on the untreated sites.

Based on the IR spectra of the test substance, wavelengths of 1746, 1466, and 1163 cm^{-1} were chosen for analysis. Presence of Mink Oil in each of the four scans (surface, 5, 10, 15 layers all done at 1 h post treatment) was defined as a greater absorbance value at the treated site versus the control. For each of the four scans, there were 15 absorbance pairs (a pair consisting of an absorbance value for the control and treated sites). Mink Oil was detected at the surface scan of all panelists. It was detected within 5 layers in 4/5 panelists, 10 layers in 2/5 panelists, and 15 layers in 2/5 panelists. The authors concluded that, after 1 h, Mink Oil remains on the skin surface (Xienta Institute for Skin Research 1988).

Distribution, Metabolism, and Excretion

No studies were available describing the distribution, metabolism, or excretion of Mink Oil.

ANIMAL TOXICOLOGY

Acute Oral Toxicity

A commercial preparation of Mink Oil had an oral LD_{50} of >64.0 cc/kg in albino rats (Bio-Toxicology Laboratories, Inc. 1974). In another study, a Mink Oil cream had an oral LD_{50} of >5.0 ml/kg in rats (Wells Laboratories, Inc. 1990e).

TABLE 3
Frequency of use of Mink Oil

Product category (number of formulations in category) (FDA 2001)	Number of formulations containing Mink Oil (FDA, 2001)	Concentration of use (CTFA 1999c, 2001) (%)
Baby lotions, oils, powders, and creams	—	1
Other bath preparations (193)	1	0.1
Eye shadow	—	0.1
Eye lotion (23)	1	—
Mascara (187)	1	0.3–1
Other fragrance preparations	—	1
Hair conditioner (630)	14	3
Hair spray—aerosol fixatives (267)	3	—
Hair straighteners (63)	4	—
Permanent waves (211)	1	—
Rinses—noncoloring	—	3
Shampoos—noncoloring (851)	4	—
Tonics, dressings, and other hair-grooming aids (577)	9	—
Other hair preparations (276)	4	—
Blushers—all types	—	0.1
Face powders (301)	1	0.1
Lipstick (942)	12	0.001
Makeup bases	—	0.5
Shaving cream (133)	5	—
Skin cleansing products (733)	7	—
Face and neck creams, lotions, powders and sprays—excluding shaving products (304)	2	0.2–0.5
Body and hand creams, lotions, powders and sprays—excluding shaving products (827)	10	0.1
Moisturizing (881)	8	0.2
Night products (200)	5	—
Paste masks—mud packs (269)	1	—
Other skin care preparations (715)	6	—
Suntan gels, creams, liquids (131)	1	0.3
Other suntan preparations	—	2
2001 total uses/ranges for Mink Oil	100	0.001–3

Dermal Irritation

Patches containing 0.5 ml of a commercial preparation of refined Mink Oil were applied to intact and scarified areas of guinea pig skin. The treatment areas had earlier been clipped free of hair. Animals were immobilized for a 24-h period; the sites were evaluated at the end of the treatment period and 24 h afterwards. Scores were made according to the Draize scale. No erythema or edema was noted (Leberco Laboratories 1972a).

Patches containing 0.5 ml of refined Mink Oil (neat) were applied to intact and abraded skin of six rabbits (strain not specified). No irritation was noted at observations made 24 and 72 h after application (Wells Laboratories, Inc. 1979b). Similar results were reported by Wells Laboratories, Inc. (1990d) when a cream containing Mink Oil was tested on three New Zealand white rabbits using the same protocol.

Dermal Sensitization

Over a period of 20 days, eight male guinea pigs received 10 subcutaneous injections of a 0.1% suspension of refined Mink Oil; the injections were administered to the clipped back and sides. The test material was suspended in physiological saline and was administered in 0.1 ml doses except for the first injection, which contained 0.05 ml. Two weeks after the final induction injection, a test injection of 0.05 ml was

administered. Reaction areas were measured 24 h after each injection. Irritation reactions were noted throughout the induction period. The reaction on challenge was less than the irritant reaction seen during induction and the authors concluded that the test material was not a sensitizer (Leberco Laboratories 1972b).

CTFA (1983) reported a study in which female Dunkin-Hartley guinea pigs were treated with Mink Oil using the Magnusson-Kligman maximization procedure: induction, dose range, booster, and challenge. During induction, sites on the upper back were injected intradermally with 50% Freund's complete adjuvant, 5% Mink Oil in propylene glycol, and 5% Mink Oil in 50% Freund's complete adjuvant. Control animals were injected with complete adjuvant, propylene glycol, and 1:1 propylene glycol in complete adjuvant. During the dose range phase, 10 animals were tested with 24 h occlusive patches containing 25%, 50%, and 100% Mink Oil. Sites were evaluated for irritation at 24, 48, and 72 h after patch application. Two of the animals reacted to the 25% concentration with a response graded as "barely perceptible"; by 72 h the condition cleared. These two animals also reacted to the higher concentrations of Mink Oil; the reactions cleared by the 72-h observation. Another four had "barely perceptible" or "mild" reactions to the 50% concentration. These reactions also cleared by 72 h and three of these four animals did not react to the 100% concentration. Three animals reacted for the first time to the 100% concentration with a "barely perceptible" response (two also had desquamation); these conditions cleared by 72 h.

During the booster phase (1 week after induction injections) undiluted Mink Oil was topically applied. Sodium lauryl sulfate (SLS) at 5% was applied to the induction site 24 h before the booster. Control animals were pretreated with SLS before receiving a booster of undiluted petrolatum; positive controls were treated with 25% phenylacetaldehyde without SLS pretreatment. During the booster phase, all test and control animals were wrapped occlusively for 48 h. Two weeks following the booster, test animals were challenged with a 24-h occlusive patch of 25% and 50% Mink Oil in petrolatum. Reactions were scored at 48 and 72 h after patch application. There were no reactions to 25% Mink Oil noted in the ten animals at the 48-h reading; one animal had a "barely perceptible" reaction at 72 h. Four animals had a "barely perceptible" and one had a "mild" response to 50% Mink Oil at the 48-h reading. At the 72-h reading, erythema was noted in 7 of 10 animals, which ranged from "barely perceptible" (4 animals) to "desquamation" (2 animals) and "mild with desquamation" (1 animal). Mink Oil at 50% in petrolatum was considered to produce a weak allergenic response (CTFA 1983).

The Buehler Technique was used by Wells Laboratories (1990a) in a guinea pig sensitization assay. During induction nine occlusive patches containing 0.5 ml of a 50% dilution (in corn oil) of a Mink Oil cream was applied to the clipped back and flank of 10 animals. The patches remained for 6 h of contact and readings were made at the time of patch removal and at the end of 24 h. Positive controls were treated with dinitrochlorobenzene (DNCB). After a 2-week nontreatment period animals were challenged with two identical applications of the test material. One patch was applied at the site of induction, and the other on a previously unexposed site. Challenge patches were applied for 6 h of contact and observations were made at the time of patch removal and at the end of 24 h. A reading of "very slight" erythema was noted in all animals during induction; "slight" erythema and "slight" edema were noted in positive controls. During challenge, no irritation was noted in animals of the Mink Oil group; marked erythema and very slight edema was noted in animals of the positive-control group.

Ocular Irritation

A commercial preparation of refined Mink Oil (0.1 ml) was instilled into the right conjunctival sac of three albino rabbits. The untreated left eye served as control. Eyes were evaluated every 24 h for 4 days and then again on the 7th day. Scores were made according to the Draize scale. No irritation was noted (score 0) (Leberco Laboratories 1972c).

Another ocular irritation test was conducted using three rabbits and the above described protocol (Wells Laboratories 1979a). Undiluted Mink Oil (commercial preparation, dose not reported) did not produce any observable irritation.

A Mink Oil cream (0.1 ml) was applied to one eye of each of three New Zealand white rabbits. The contralateral eye was not treated and served as control. Eyes were unwashed for 24 h and observations made 24, 48, and 72 h after treatment. No irritation was noted (Draize score 0.01) (Wells Laboratories, Inc. 1990c).

Comedogenicity

A Mink Oil cream was considered to be noncomedogenic following repetitive applications (10 applications in 2 consecutive weeks) to the external ear canal of six albino rabbits. Observations noted include "minimal to mild" hyperemia and "very minimal" hyperkeratosis in the treated areas of all animals towards the end of the treatment period (Wells Laboratories, Inc. 1990b).

CLINICAL ASSESSMENT OF SAFETY

Dermal Irritation and Sensitization

Twenty panelists received a single 24-h occlusive patch containing a 25% aqueous dilution of a hair rinse containing 3% Mink Oil (effective concentration of Mink Oil tested: 0.75%). No reactions were noted in 16 panelists, reactions of $\pm$ (the mildest non-zero score possible) were noted in four panelists. The primary irritation index (PII) was 0.10 out of a maximum possible score of 4.0 (CTFA 1989). Identical results were reported in a second patch test study in which a formulation containing 2.8% Mink Oil was tested at full strength in 20 panelists (CTFA 1992a). A third human patch test study reported a PII of

0.08 after 19 panelists were tested with a (full-strength) formulation containing 2.8% Mink Oil (CTFA 1993).

A 4-day minicumulative patch test of a body spray containing 1% Mink Oil had a PII of 0.50. Of 20 panelists, 5 had no response, 12 had a "barely perceptible" response, 2 had a "mild" response, and 1 had a "moderate" response (CTFA 1991).

In an exaggerated-use study, 19 female panelists applied to the lower arm, a rinse-off hair product containing 2.8% Mink Oil once a day for 5 days with no rinse off. A commercially available rinse-off hair product was applied to a different site to serve as a reference. Four subjects experienced some transient mild to moderate erythema (CTFA 1992b). In a second study using the same protocol, no clinical responses were observed in 24 females who also tested a rinse-off hair product containing 2.8% Mink Oil (CTFA 1994).

Sun-Protection Factor

Wells Laboratories (1988a, 1988b) tested the sunscreening ability of Mink Oil. In six subjects, 20% Mink Oil with 3% Octyl Dimethyl PABA and 77% Isopropanol had a sun-protection factor (SPF) value of 5.36. In five subjects, a preparation containing Mink Oil had an SPF value of 2.2. Further study details and the specific light source used were not reported.

SUMMARY

Mink Oil, obtained from the fatty tissues of minks, is a mixture of the natural glycerides of 14 to 20 carbon chain fatty acids. In 2001, it was reportedly used in 100 cosmetic formulations as a hair-conditioning agent, an occlusive skin-conditioning agent, and as a surfactant at concentrations no greater than 3%.

Mink Oil is manufactured by harvesting animal hides and scraping the fat layer from the hide. It is rendered and refined using high temperature processes (230°F to 240°F) and saponification to reduce free fatty acids.

Most of the glycerides in Mink Oil are triglycerides, the safety of which has substantially assessed in previous safety assessments; e.g., dermal absorption is nil to slight; there is little or no acute, subchronic, or chronic oral toxicity; dermal application was not associated with significant irritation or sensitization; ocular exposures were, at most, mildly irritating; most of the genotoxicity test systems are negative; use as vehicles in carcinogenicity testing of other chemicals has produced no adverse reaction; and clinical tests produce no irritation or sensitization reactions—but, they may enhance the penetration of other chemicals.

Analyses demonstrate that Mink Oil can be substantially free of impurities, including pesticides. Mink Oil does not absorb significant UVA or UVB radiation.

An attenuated total reflectance–infrared spectroscopy study found that 1-h after application, Mink Oil was detected on the skin surface of all five panelists; it was detected within the stratum corneum in 2/5 panelists.

Mink Oil has an oral LD_{50} of >64.0 cc/kg in albino rats.

No erythema or edema was noted after refined Mink Oil was applied for 24 h to intact and scarified area of albino rabbits.

Although reactions were noted during induction, a 50% dilution of a Mink Oil cream did not sensitize guinea pigs using the Buehler technique. In a second study, using the Magnusson-Kligman maximization procedure, 50% Mink Oil in petrolatum-induced sensitization reactions.

Mink Oil was not an ocular irritant to albino rabbits.

Clinical studies using single occlusive patches found no irritation with up to 2.8% Mink Oil (PII scores of 0.08 to 0.10). Transient mild to no irritation was noted in two exaggerated-use studies.

DISCUSSION

The CIR Expert Panel had previously issued a final safety assessment of Mink Oil with an insufficient data conclusion. The Panel has now considered information on the manufacturing process; batch analysis data; pesticide residue analysis; updated concentration of use; and UV absorption spectra newly provided by industry.

The Panel noted that Mink Oil is used in aerosols and sprays. Although there are no inhalation toxicity data available on Mink Oil, the available data on particle sizes of cosmetic aerosols and sprays indicate diameters more than an order of magnitude larger than the diameter of respirable particles. Inhalation, therefore, is not believed to produce significant exposure of lung tissue.

It was noted that most of the glycerides in Mink Oil are triglycerides, and the Panel agreed that the safety test data in the triglycerides safety assessment are relevant to Mink Oil. The triglycerides data demonstrate, among other things, that dermal absorption of triglycerides is nil to slight; there is little or no acute, subchronic, or chronic oral toxicity; dermal application is not associated with significant irritation or sensitization; ocular exposures are, at most, mildly irritating; most genotoxicity test system results are negative; use as vehicles in carcinogenicity testing of other chemicals has produced no adverse reaction; and clinical tests produce no irritation or sensitization reactions. Because triglycerides may enhance the penetration of other chemicals, it has been recommended that care be exercised in using them in cosmetic products. That same caution should be applied to Mink Oil.

Although pesticide residues have been analyzed and found to be below levels of detection, the Panel is concerned that the available data suggesting the absence of pesticide residues in Mink Oil are limited. The Panel advised the industry that the total PCB/pesticide contamination should be limited to not more than 40 ppm, with not more than 10 ppm for any specific residue. As with any animal-derived ingredient, Mink Oil should be free of detectable pathogenic viruses or infectious agents.

The CIR Expert panel recognizes that Mink Oil is reportedly used in some product categories, but that the concentration of

use is not available. In other cases, information regarding use concentration for specific product categories is provided, but the number of such products is not known. Although there are gaps in knowledge about product use, the overall information available on the types of products in which Mink Oil is used and at what concentration indicate a pattern of use. Within this overall pattern of use, the Expert Panel considers Mink Oil to be safe.

CONCLUSION

Based on the available information, the CIR Expert Panel concludes that Mink Oil is safe as a cosmetic ingredient in the practices of use and concentration described in this safety assessment.

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