


Final Report of the Safety Assessment of Cosmetic Ingredients Derived From Zea Mays (Corn)

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Abstract

Many cosmetic ingredients are derived from *Zea mays* (corn). While safety test data were not available for most ingredients, similarities in preparation and the resulting similar composition allowed extrapolation of safety data to all listed ingredients. Animal studies included acute toxicity, ocular and dermal irritation studies, and dermal sensitization studies. Clinical studies included dermal irritation and sensitization. Case reports were available for the starch as used as a donning agent in medical gloves. Studies of many other endpoints, including reproductive and developmental toxicity, use corn oil as a vehicle control with no reported adverse effects at levels used in cosmetics. While industry should continue limiting ingredient impurities such as pesticide residues before blending into a cosmetic formulation, the CIR Expert Panel determined that corn-derived ingredients are safe for use in cosmetics in the practices of use and concentration described in the assessment.

Keywords

cosmetics, safety, *Zea mays* (corn)

Introduction

Various cosmetic ingredients are derived from *Zea mays* (Corn) plants. These include oils, cob meal, cob powder, corn acid (fatty acids) and its potassium salt, corn glycerides and oil unsaponifiables, fruit, germ extract and oil, gluten protein, hydrolyzed starch and protein, kernel extract and meal, seed flour, starch, and silk extract.

While safety test data that directly examine toxicity are available for several of these ingredients, they are not available for all. Extensive data are available for corn oil as a result of its use as a vehicle in studies that examine the toxicity of another entity.

In addition, corn oil has been used as a component of diet in studies that examine the effects of high fat content in the diet; for example, the effect of starch in the diet on growth of foci of dysplastic crypts in the colon. Representative dietary studies are provided.

- Zea Mays (Corn) Cob Meal (no CAS number available) is the milled powder prepared from the cobs of *Zea mays* that functions as an abrasive and bulking agent.
- Zea Mays (Corn) Cob Powder (no CAS number available) is the powder obtained from the dried ground cobs of *Zea mays* that functions as an abrasive.
- Zea Mays (Corn) Fruit (no CAS number available) is the fruit of *Zea mays* that has no defined function in cosmetics.
- Zea Mays (Corn) Germ Extract (no CAS number available) is an extract of the germ of the corn, *Zea mays* that has no defined function in cosmetics.
- Zea Mays (Corn) Germ Oil (no CAS number available) is the oil obtained from the germ of *Zea mays* that functions as an occlusive skin conditioning agent.
- Zea Mays (Corn) Oil (CAS #8001-30-7) is the refined fixed oil obtained from the wet milling of corn *Zea mays* that functions as a fragrance ingredient, hair conditioning agent,

Chemistry

Definition

The *International Cosmetic Ingredient Dictionary and Handbook* defines these ingredients and gives their functions in cosmetics as follows¹:

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occlusive skin conditioning agent, surfactant–emulsifying agent.

- Zea Mays (Corn) Oil Unsaponifiables (no CAS number available) is the fraction of Zea Mays (Corn) Oil (qv), which is not saponified in the refining recovery of corn oil fatty acids, that functions as a hair conditioning agent and skin conditioning agent—miscellaneous.
- Zea Mays (Corn) Gluten Protein (CAS #66071-96-3) is a protein obtained from the starchy endosperm of corn, *Zea mays* that functions as a bulking agent, hair conditioning agent, and skin conditioning agent—miscellaneous.
- Zea Mays (Corn) Kernel Extract (no CAS number available) is an extract of the kernels of corn, *Zea mays* that has no defined function.
- Zea Mays (Corn) Kernel Meal (CAS #66071-96-3) is the coarse flour prepared by milling the kernels of *Zea mays* that functions as an abrasive and bulking agent.
- Zea Mays (Corn) Seed Flour (CAS #68525-86-0) is the powder prepared from the fine grinding of the inner portion of the seeds of *Zea mays* that functions as an abrasive, absorbent, binder, and bulking agent.
- Zea Mays (Corn) Silk Extract (no CAS number available) is an extract of the stigmas of the corn, *Zea mays* that has no defined function.
- Zea Mays (Corn) Starch (CAS #9005-25-8) is a starch obtained from corn, *Zea mays*, that functions as an abrasive, absorbent, skin protectant, and aqueous viscosity increasing agent.
- Hydrolyzed corn starch (no CAS number available) is the hydrolysate of Zea Mays (Corn) Starch (qv), derived by acid, enzyme, or other method of hydrolysis, that functions as a skin conditioning agent—humectant.
- Hydrolyzed Corn Protein (CAS #73049-73-7) is a hydrolysate of corn protein, derived by acid, enzyme, or other method of hydrolysis that functions as a hair conditioning agent and skin conditioning agent—miscellaneous.
- Corn Acid (CAS #68308-50-9) is a mixture of fatty acids derived from Zea Mays (Corn) Oil that functions as an opacifying agent and surfactant—cleansing agent.
- Potassium Cornate (CAS #61789-23-9) is the potassium salt of Corn Acid that functions as a surfactant—cleansing agent.
- Corn Glycerides (no CAS number available) is a mixture of mono, di, and triglycerides derived from Zea Mays (Corn) oil which functions as a skin conditioning agent—humectant and surfactant—emulsifying agent.

Zea Mays (Corn) Fruit can be considered as all edible crop tissues (fruit) of *Zea mays*.²

Zea Mays (Corn) oil or corn oil is a mixture consisting of glycerides of the following fatty acids: myristic 0.1% to 1.7%, palmitic 8% to 12%, stearic 2.5% to 4.5%, hexadecenoic 0.2% to 1.6%, oleic 19% to 49%, and linoleic 34% to 62%. The unsaponifiable fraction comprises 1% to 3% of the mixture. The crude oil may contain up to 2% phospholipids.³

Zea Mays (Corn) Starch is a carbohydrate polymer derived from corn of various types, composed of 25% amylase and 75% amylopectin.^{4,5}

Table 1. Physical and Chemical Properties of Corn Oil

| Property | Description/Value |
|----------------------|--|
| Color | Yellow ^a Pale-yellow ^b |
| Odor and taste | Faint ^a Characteristic ^b |
| Density | 0.916-0.921 ^a 0.914-0.921 ^b |
| Melting point | -18°C to -10°C ^a -10°C ^b |
| Flash point | 321°C ^a 254°C ^b |
| Ignition point | 393°C ^{a,c} |
| Acid value | 2-6 ^a |
| Saponification value | 187-196 ^a |
| Iodine value | 109-133 ^a 102-128 ^b |

^a Budavari 1989³

^b Lewis 1997⁵

^c Lewis 1993¹⁴

Hydrolyzed corn starch can be considered the end product of starch-water treatment with dilute mineral acid. The acid modification reduces chain length but does not substantially change the molecular configuration.⁶

Although Zea Mays (Corn) Germ Oil and Zea Mays (Corn) Oil are listed in the *International Cosmetic Ingredient Dictionary and Handbook* as separate ingredients, the Corn Refiners Association reports that all Corn oil is made from corn germ (Corn Refiners Association, personal communication 2006). The additional term “Germ” is only to denote that a specific part of the plant was used in the manufacture of the cosmetic ingredient in the *International Cosmetic Ingredient Dictionary and Handbook* (Gottschalck, personal communication 2006).

For the sake of brevity, this report will use Corn instead of repeatedly spelling out Zea Mays (Corn). And corn oil will be used for both corn oil and corn germ oil.

Physical and Chemical Properties

Physical and chemical property information found on corn oil is given in Table 1.

Corn Silk Extract is a slightly viscous brown liquid with a pH of 4.5 to 6.5.⁷

Physical and chemical property information on Corn Cob Meal was available for a trade name ingredient, Grit-o’cob, which is made from the woody ring of the corncob. This product is 84.4% structural polysaccharides and 7% water. Grit-o’cob includes 36.9% crude fiber and 53.3% nitrogen-free extract (carbohydrates). Cellulose makes up 47.1% of the total, along with 37.3% hemicellulose. Of the total, 39.9% are hexosan, 36.5% are pentosan, and 31.6% are xylan. Physical and chemical properties and trace components for Grit-o’cob appear in Table 2.

Table 2. Physical and Chemical Properties and Composition of a Tradename Corn Cob Meal, Grit-o'cob Granules⁸

| Property | Value ^a |
|---------------------------------|---------------------------|
| Water absorption | 133% |
| Bulk density | 28.0 lbs/ft ³ |
| Specific gravity | 1.3 |
| Surface area | 5.85 m ² /g |
| Solubility in: | |
| Acetone | 2.5% |
| Ethanol | 1.6% (2 h) |
| Isopropyl alcohol | 0.42% |
| 1% potassium hydroxide | 18.6% |
| 10% sulfuric acid | 2.5% |
| Hot water | 9.5% |
| Room temperature Water | 6.3% |
| Cation exchange Capacity | 0.85 meq/g |
| Gross energy | 4113 kcal/kg ^b |
| Total microorganism plate count | 10,500/g |
| Coliform | Negative |
| Salmonella | Negative |
| Mold and yeast | 80/g |
| Average particle diameter | 0.00849-0.1785 |
| Trace elements ^c | |
| Nitrogen | 0.21% |
| Phosphorus | 0.021% |
| Sulfur | 0.013% |
| Potassium | 0.93% |
| Sodium | 0.14% |
| Magnesium | 0.11% |
| Silicon | 0.089% |
| Iron | 0.013% |
| Calcium | 0.011% |
| Aluminum | 0.0053% |
| Selenium | <5ppb |
| Fat | 0.2% |
| Protein | 1.4% |
| Ash | 1.2% |
| Vitamin A equiv | 0.9 IU/g ^b |
| Carotene | 0.5 mg/kg ^b |
| Biotin | 0.02 µg/g |
| Niacin | 6.8 µg/g |
| Pantothenic acid | 2.5 µg/g |
| Pyridoxine | 3.1 µg/g |
| Riboflavin | 1.1 µg/g |

^a Normalized to a 7% moisture basis.^b Estimated.^c Barium, chromium, copper, lead, manganese, nickel, vanadium, and zinc all <0.0001%.

A phytochemical and ethnobotanical database lists the chemicals expected to be present in various plant materials (Table 3).

Methods of Manufacture

Information on methods of manufacture are included where available:

Corn gluten protein (listed as corn gluten in the Code of Federal Regulations [CFR]) is produced as a byproduct

during the wet milling of corn for starch in whole or various fractions of dry milled corn to corn syrups (21CFR 184.1321).

Corn oil is usually extracted from the clean, dried corn germ by wet milling. Corn oil is produced by a combination of expelling in continuous screw presses and solvent extraction of the press cake. The initial expeller can recover a little more than half of the oil and subsequent solvent extraction with hexane, the preferred solvent, brings total yield to about 95%.

Corn silk extract is produced by dilute ethanol extraction of corn silk, the fresh styles and stigmas of *Zea mays* collected when the corn is in milk (21CFR 184.1262).

The raw herbal material is made into an extract using the percolation method with heated water. After soaking for approximately 12 hours, the liquid is extracted and filtered to remove insoluble material. Corn Silk Extract obtained and distilled by this method is blended with alcohol and water.¹⁰ This mixture is then heated and allowed to cool.

Corn starch is produced by softening cleansed corn with warm water containing dissolved sulfur dioxide to soften the kernel.⁶ Sulfur dioxide and water react to form sulfurous acid, which assists in separation of starch and protein. Softened corn kernels next pass through mild attrition mills to loosen the hull and free the germ from the starch-rich endosperm. Water is added to the attrition mills, and a thick slurry of macerated kernels and whole germ results. Because the germ at this stage contains 40% to 50% oil, it is lighter than the endosperm and hull. Density centrifugation is used to isolate the germ. The remaining mixture of hull and endosperm is ground and screened. Large hull particles are retained on screens and removed, while finer protein and starch particles pass through. The water slurry of starch and gluten protein is separated by centrifugation—nearly complete separation is achieved. Typical yields include a gluten stream containing over 60% protein, while the starch stream is greater than 99% starch. The white, nearly pure starch slurry is further washed to remove small quantities of solubles.

Hydrolyzed corn starch is produced by treating the slurry of washed starch (described above) with dilute mineral acid at temperature elevated but below the starch gelatinized temperature, for varying periods of time. The primary reaction taking place is hydrolysis of glucosidic bonds in starch molecules. At the desired viscosity, the acid is neutralized with sodium carbonate and the starch is filtered, washed, and dried.⁶

Analytical Methods

Adulteration of corn oil can be detected by the principal component scores of the $\delta^{13}\text{C}$ values of major and minor vegetable oil components.¹¹ This analytical method is based on the premise that each plant species has a unique pattern of naturally occurring stable isotopes of carbon, hydrogen, and oxygen and that variations between isotopic compositions of different

Table 3. List of Chemicals Present in Corn Plant (Duke 2007)⁹

| Component | Chemicals Expected to be Present | | | |
|---------------|---|--|-----------------------------------|-----------------------------|
| Anther | Peroxidase | Lignin | pantothenic-acid | |
| Cob | 4-hydroxybenzaldehyde | Niacin | p-hydroxybenzaldehyde | pyridoxine riboflavin |
| | Biotin | | | |
| | Hemicellulose | Tryptophan | | |
| Cotyledon | Indole-3-acetic-acid | | heptan-2-ol | |
| Embryo | Histidine | Bisabolol | Fructose | Oxalic-acid |
| Endosperm | Protease inhibitor C1-4-A | Campestanol ferulate | Glucose | Palmitoleic-acid |
| Essential Oil | 2-ethyl-1-cyclohexen-1-yl | Campestanol-p-coumarate | Glutathione | Phylloquinone |
| Fruit | 4-acetyl-benzoxazolin-2-one | Chlorine | Glutelin | Raffinose |
| | α -tocopherol | Cobalt | Lignoceric-acid | Riboflavin |
| | Amino acids | Copper | | |
| | Campestanol ferulate | Folacin | | Protease inhibitor |
| | Campestanol-p-coumarate | | | |
| | Chlorine | Gamma-tocopherol | Phylloquinone | |
| Oil | Alpha-tocopherol | | | |
| Pericarp | Chrysanthemin | | | |
| Plant | 2-(2,4-dihydroxy-7-methoxy-1,4(2h)-benzoxazin-3(4h) | Amino-adipic-acid | Galactose | Myo-inositol |
| | 24-methylene-cycloartenol | Apigenin-glycoside | Galactoxylase | |
| | 3-o-cafeoylquinic-acid | Arabinose | Gamma-sitosterol | Myrecitin-glucoside |
| | 3-o-coumarylquinic-acid | Arachidic-acid | Glutamic-acid-decarboxylase | Neocryptoxanthin |
| | 4-vinyl-4-deethyl-chlorophyll-a | Beta-amylase | Glycerol | Pectins |
| | 5-hydroxy-trans-ferulic-acid | Beta-zeacarotene | Guanidine | Pelargonidin-3-glucoside |
| | 5-o-cafeoylquinic-acid | Beta-zein | Inositol | Phenylalanine-ammonia-lyase |
| | 5-o-coumarylquinic-acid | Cadaverine | Isoquercitrin | Phosphatidyl-choline |
| | 5-o-feruloylquinic-acid | Cellulose | Lactic-acid | Phosphatidyl-ethanolamine |
| | 6-methoxy-benzoxazolin-2-one | Coixol | Lanosterol | Phosphatidyl-inositol |
| | 6, 7-dimethoxy-benzoxazolin-2-one | Cryptoxanthin | Leucocyanidin | Phytin |
| | Acetoin | Cyanidin-3-galactoside-p-coumaric-acid-ester | Leucopelargonidin | Phytofluene |
| | | | | Quercetin-diglucoside |
| | Aflatoxin B-1 | Cyanidin-3-monoside | Linalool | |
| | Aflatoxin | Cystathione | Lipoxidase | Quinic-acid |
| | Aldobiouronic-acid | Cytochrome-c | Maleic-acid | Ricinoleic-acid |
| | Alpha-amylase | D-glucuronic-acid | Malic-acid-dehydrogenase | Rubisco |
| | Alpha-amyrin | Dec-trans-2-cis-4-dien-1-al | Malonic-acid | |
| | Alpha-glucosidase | Dihydroxystosterol | Maltosyl-transferase | |
| | Alpha-sitosterol | Dioxycinnamic-acid | Mannose | |
| | Alpha-zeacarotene | Furfural | Monogalactosyl-diglyceride | |
| Seed | 1-p-hydroxy-trans-cinnamoyl)-glycerol | Calcium | Indole-3-acetic-acid-myo-inositol | Vit-b-6 |
| | 28-norcastosterone | Calmodulin | Indole-3-butyric-acid | Water |
| | 3-7-dihydroxy-indolin-2-one-3-acetic Acid | Campesterol | Iodine | Ytterbium |
| | 7'-o-beta-glucoside | | | |

(continued)

Table 3. (continued)

| Component | Chemicals Expected to be Present | Carvacrol | Iron | Phosphorus | Zea Mays Alpha-amylase Inhibitor |
|--------------------|--|--|---|--|---|
| | 4-ethyl-guaiacol | Castasterone Chitinase B Chitinase a Cholesterol Choline Chromium | Isobehenic-acid Isoleucine Isopropyl-amine Lead Leucine Linoleic-acid | Phytate Phytic-acid Phytosterols Potassium Prolamine Proline | Zeamatin Zeanin Zeanoside a Zeanoside-b Zeanoside-c Zeaxanthin |
| | 4-ethylphenol 4-methyl-guaiacol 4-vinyl-guaiacol 4-vinyl-phenol 6-deoxocastasterone 8-hydroxy-quinol-2-one-4-carboxylic- acid-8'-o-beta-d-glucoside | Chrysanthemin Cystine Diethyl-amine Digalactosyl-diglyceride Dimethyl-amine Ethyl-amine Ethyl-methyl-amine Eugenol Fat Ferulic-acid Fixed-oil Folic-acid Gamma-carotene Globulin Glutamic-acid Glutathione Gluten Glycine Guaiacol Hexadecenoic-acid Hexenyl-isothiocyanate Histidine Indole-3-acetic-acid-cellulosiluglan Indole-3-acetic-acid-methyl-ester Decan-2-one Geosmin Geranyl-acetone Hept-4-en-2-ol Hept-4-en-2-one Heptan-1-ol Heptan-2-ol Alpha-tocopherol Beta-sitosterol | Lithium Lutein+Zeaxanthin Lysine Magnesium Manganese Melatonin Mercury Methionine Methyl-amine Mevalonic-acid Molybdenum Myristic-acid N-demethyl-diazepam N-methyl-beta-phenethylamine N-methyl-phenethylamine N-propyl-gallate Niacin Nickel Octadecadienoic-acid Octadecatrienoic-acid Octadecenoic-acid Oleic-acid P-coumaric-acid Palmitic-acid Heptan-2-one Hexan-1-al Hexan-1-ol Hexan-2-one Limonene Myrcene Naphthalene Cyclosadol Estrone | Protein Pyrrolidine Selenium Silver Sodium Spermidine Spermine Starch Stearic-acid Stigmasterol Strontium Teasterone Threonine Tin Titanium Tocopherols Trans-ferulic-acid Trigonelline Tryptophan Tyrosine Uridine Valine Vanadium Vanillin Non-cis-3-en-1-ol Nonan-1-al Nonan-1-ol Nonan-2-ol Nonan-2-one Oct-1-en-3-ol Octan-1-ol Squalene Stigmasterol | Zein Zeta-carotene Zinc Zirconium |
| Seed essential oil | 2-methyl-naphthalene 2-pentyl-furan Alpha-ylangene Carvacrol Deca-trans-2-cis-4-dien-1-al Deca-trans-2,trans-4-dien-1-al Decan-2-ol 24-methyl-23-dehydro-cholesterol 5-dehydro-avenasterol | | | | Octan-2-ol Octan-2-one Phenyl-acetaldehyde Thymol Undecan-2-ol |
| Seed oil | | | | | |

(continued)

Table 3. (continued)

| Component | Chemicals Expected to be Present | Campesterol | Protosan | Trans-24-methyl-23-dehydro- |
|--------------------|---|------------------------------------|---------------------------------------|---------------------------------|
| Shoot | 7-dehydro-avenasterol | Campesterol | | lphenol |
| | 2-o-p-coumaroyl-hydroxy-citric-acid | 6,10,14-trimethyl-pentadecan-2-one | Campesterol | Ethyl-acetate |
| | 24-ethylidene-lophenol | Aconitic-acid | Cholesterol | Friedelin |
| | 24-methylene-cycloartanol | Benzaldehyde | Choline | Furfural |
| | 24-methylene-lophenol | Beta-amyrin | Cycloartenol | Hex-cis-3-en-1-ol |
| | 6-methoxy-2-(3)-benzoxazolinone | Beta-sitosterol | Cycloeculenol | Hexan-1-al |
| | 6-methoxy-benzoxazolin-2-one | Betaine | Ent-17-hydroxy-kaur-15-en-19-oic acid | Indole |
| | | | Ent-kaur-15-en-17-beta-ol | |
| Silk essential oil | 10-oxo-octadec-trans-11-en-13-olide seed 0.3 20426 | Caffeic-acid | Glycolic-acid | Isovaleraldehyde |
| | 1,2-dimethyl-4-ethyl-benzene | Beta-pinene | Gum | Menthyl |
| | 1,2,3-trimethyl-benzene | Beta-sitosterol | Hept-4-en-2-ol | Methyl-phenylacetate |
| | 1,2,4-trimethyl-benzene | Betaine | Hept-cis-4-en-2-ol | Naphthalene |
| | 1,3-dimethyl-4-ethyl-benzene | Biphenyl | Hept-trans-2-en-1-al | Naphthalene |
| | 1,8-cineol | Butan-1-ol | Hepta-trans-2-cis-4-dien-1-al | Niacin |
| | 2"-o-alpha-rhamnosyl-6c-(6-deoxo-xylo-hexos-4-ulosyl)-apigenin | Calcium | Hepta-trans-2-en-1-al | Non-trans-2-en-1-al |
| | 2"-o-alpha-rhamnosyl-6c-(6-deoxo-xylo-hexos-4-ulosyl)-chrysoeriol | Carbohydrate | Hepta-trans-2-trans-4-dien-1-al | Nona-trans-2-trans-4-dien-1-al |
| | 2"-o-alpha-l-rhamnosyl-6-c-fucosyl-3'-methoxy-luteolin | Carvacrol | Heptan-1-al | Nonal-n-2-ol |
| | 2"-o-alpha-l-rhamnosyl-6-c-fucosyl-luteolin | Chlorogenic-acid | Heptan-1-ol | Nonan-1-al |
| | 2"-o-alpha-l-rhamnosyl-6-c-quinovosyl-luteolin | Chromium | Heptan-2-ol | Nonan-1-ol |
| | 2-ethyl-hex-an-1-ol | Cinnamic-acid-ethyl-ester | Heptan-2-ol | Nonan-2-ol |
| | 2-methyl-butan-1-al | Cobalt | Hex-1-en-3-ol | Nonan-2-one |
| | 2-methyl-butan-1-ol | Daucosterol | Hex-cis-3-en-1-ol | O-diethyl-phthalate |
| | 2-methyl-naphthalene | Dec-trans-2-cis-4-dien-1-al | Hex-cis-3-en-1-ol | Oct-1-en-3-ol |
| | 2-methyl-pentan-3-one | Dec-trans-2-en-1-al | Hex-trans-2-en-1-al | Oct-1-en-3-ol |
| | 2-methyl-propan-1-ol | Dec-trans-2-trans-4-dien-1-al | Hex-trans-2-en-1-ol | Oct-trans-2-en-1-al |
| | 2-pentyl-furan | Deca-trans-2-cis-4-dien-1-al | Hex-trans-2-trans-4-dien-1-al | Oct-trans-2-en-1-ol |
| | 2-pentyl-furan | Deca-trans-2,trans-4-dien-1-al | Hex-trans-3-en-1-ol | Octa-3-5-dien-2-one |
| | 3'-methoxymaysin | Decan-1-al | Hexa-trans-2-trans-4-dien-1-al | Octa-trans-2-trans-5-dien-2-one |
| | 3'-o-methyl-maysin | Decan-1-ol | Hexan-1-al | Octan-1-ol |
| | 3-methyl-butan-1-ol | Decan-2-ol | Hexan-1-ol | Octan-1-ol |
| | Alkaloids | Ergosterol | Hexan-1-ol | Octan-2-ol |
| | Alpha-terpineol | Ethanol | Hexan-2-ol | Oleanolic-acid |
| | Aluminum | Ethyl-acetate | Hordeoline | Orientin |
| | Apiforol | | Iron | Palmitic-acid |

(continued)

Table 3. (continued)

| Component | Chemicals Expected to be Present | | | | |
|-----------------|----------------------------------|----------------------------|---------------------|----------------------|----------------------------|
| Sprout seedling | Apigenidin | Ethyl-phenylacetate | Limonene | Pelargonidin | Zea glycoprotein u-cse-100 |
| | Ascorbic-acid | Fat | Limonene | Pent-1-en-2-ol | Zea glycoprotein u-cse-300 |
| | Ash | Fiber | Luteoforol | Pentan-1-ol | |
| | Benzaldehyde | Fluorene | Luteolinidin | Pentan-2-ol | |
| | Beta-carotene | Gamma-nonolactone | Magnesium | Pentan-3-one | |
| | Beta-ionone | Geosmin | Malic-acid | Phenethyl-alcohol | |
| | | Geraniol | Manganese | | |
| | 1,3-amino-propyl-pyrrolinium | Delta-amino-levulinic-acid | Feruloylquinic-acid | Obtusifolol | Putrescine |
| | 6-methoxy-benzoxazolin-2-one | Diamino-propane | Glucose | P-coumaric-acid | Pyruvic-acid |
| | Benzoxazone | Ethyl-amine | Isoamyl-amine | Phosphoenol-pyruvate | Vanillic-acid |
| Stem | Caffeic-acid | Ferulic-acid | | | |
| | Lignin | | | | |

species or different sources of the same species are due to isotopic fractionations arising from a variety of biochemical and environmental factors. However, before this technique can be used, it is necessary to determine the fatty acid compositions and $\delta^{13}\text{C}$ values of the major fatty acids of more than 150 vegetable oils in order to provide a database of mixing curves showing how the $\delta^{13}\text{C}$ value of a pure oil is altered as a particular adulterant oil is added.

Methods for characterization of corn starch properties including heavy metals, moisture, protein, etc and Hydrolyzed corn starch properties including pH, hydroxyethyl substitution level, etc have been reported.⁶

Impurities

Corn oil commands a premium price and is therefore a target of adulteration with cheaper vegetable oils. Detection of this activity is challenging because of the natural variability in the fatty acid composition and because of the high sterol and tocopherol contents.¹¹

Less than 0.0001% of barium, chromium, copper, lead, manganese, nickel, vanadium, and zinc has been reported in Corn Cob Meal.⁸

Use

Cosmetic

Corn-derived ingredients are defined in the *International Cosmetic Ingredient Dictionary and Handbook*, which gives the functions for these ingredients described earlier.¹ Under a voluntary reporting program (VCRP) industry provides information to the US Food and Drug Administration (FDA) on the types of products in which individual ingredients are used. An industry survey conducted by the Cosmetic, Toiletry, and Fragrance Association (CTFA), which is now the Personal Care Products Council (Council), collected current use concentration data. These data are summarized in Table 4.

Certain ingredients in this group are reportedly used in a given product category, but the concentration of use is not available. For other ingredients in this group, information regarding use concentration for specific product categories is provided, but the number of such products is not known. In other instances, an ingredient is not in current use, but may be used in the future.

For example, Corn Cob Meal was reportedly used in 1 hair straightener out of the 61 hair-straightener products reported to FDA, but no information on the concentration at which the ingredient is used was available.

If an ingredient is not included in Table 5, there were no reported uses to FDA or CTFA.

Noncosmetic

Food. Corn Fruit is consumed by humans and livestock. The CFR defines corn as grain that consists of 50% or more of whole kernels of shelled dent corn and/or shelled flint corn

(*Zea mays*) and not more than 10% of other grains (7CFR 810.401).

Corn Gluten Protein is used in food with no limitations and is listed as a Generally Recognized As Safe (GRAS) substance (21CFR 184.1)

White and Yellow Corn Meal are defined as food (21CFR 137.250, 21CFR 137.275) although they are not listed as GRAS substances.

The Food and Drug Administration (FDA), as presented in the Code of Federal Regulations (CFR), divides Corn Meal into the following groups: White, Yellow, Self-rising White, Self-rising Yellow, Degerminated White, Degerminated Yellow, Bolted White, and Bolted Yellow (21CFR 137.250, 137.275, 137.270, 137.290, 137.265, 137.285, 137.255, and 137.280).

Corn oil is used in food preparation. It is also used as a defoaming agent in the manufacture of paper and paperboard (21CFR 176.210) and as a resinous and polymeric coating (21CFR 175.300).

Corn seed flour is divided into White and Yellow Corn Flour by the CFR. Both are defined as food (21CFR 137.211, 21CFR 137.215).

Corn silk and corn silk extract are both listed as GRAS direct food substances (21CFR 184-1262).

Medical. In the United States, corn starch may be used as an active ingredient in OTC drug products, known as Topical Starch. It is used as an abrasive, absorbent, skin protectant, and a viscosity increasing agent.

In Canada, corn starch is approved for medicated skin care products in levels of less than or equal to 10%.

Toxicity

Acute Toxicity

The oral toxicity of corn kernel extract was evaluated in rats.¹⁵ Ten OFA Sprague-Dawley rats about 2 months old were used. The rats were not fed 16 hour prior to administration. A single dose of 20 mL/kg was administered via an esophageal probe. One hour after administration, there were no signs of toxicity. The animals were weighed 4, 7, and 14 days later. No signs of toxicity were observed.

Ocular Irritation

Eye irritation of Corn Kernel Extract in rabbits was evaluated.¹⁶ Three New Zealand albino rabbits were used, which were approximately 12-week-old at the beginning of the study and weighed approximately 2 kg. One tenth milliliter of pure corn kernel extract was applied directly into the lower conjunctival sinus of the right eye of each rabbit. Eye examinations were performed 1, 24, 48, and 72 hours after application, using the left eye as a control. Within 24 hours of application, slight redness of the conjunctiva and major watering of the eyes was observed in all of the animals, as well as a very slight epithelial attack of the cornea in a single animal. All of these reactions fully disappeared after 24 hours.

Table 4. Current Cosmetic Product Uses and Concentrations for Corn Ingredients

| Product Category (FDA 2008 Totals) | 2007 Uses (FDA 2007) ¹² | Use Concentration %(2006 ^a) ¹³ |
|---|------------------------------------|---|
| Zea Mays (Corn) Cob Meal | | |
| Noncoloring hair care products | | |
| Straighteners (144) | 1 | — |
| Skin care products | | |
| Cleansing creams, lotions, liquids, and pads (1368) | — | 3 |
| Face and neck creams, lotions, powders, and sprays (1195) | — | 3 |
| Other (1244) | 3 | — |
| Total uses/ranges for corn cob meal | 4 | 3 |
| Zea Mays (Corn) cob powder | | |
| Bath products | | |
| Soaps and detergents (1329) | 1 | 2 |
| Skin care products | | |
| Cleansing creams, lotions, liquids, and pads (1368) | 2 | 0.7-10 |
| Other (1244) | 2 | — |
| Total uses/ranges for Corn Cob Powder | — | 0.7-10 |
| Zea Mays (Corn) Germ Extract | | |
| Skin care products | | |
| Cleansing creams, lotions, liquids, and pads (1368) | 2 | — |
| Face and neck creams, lotions, powders, and sprays (1195) | 1 | — |
| Body and hand creams, lotions, powders, and sprays (1513) | 1 | — |
| Paste masks/mud packs (418) | 1 | — |
| Total uses/ranges for corn germ extract | 5 | — |
| Zea Mays (Corn) Germ oil | | |
| Baby products | | |
| Lotions, oils, powders, and creams (132) | 1 | — |
| Other (138) | 1 | — |
| Bath products | | |
| Soaps and detergents (1329) | 3 | 3 |
| Fragrance products | | |
| Perfumes (569) | — | 20 |
| Noncoloring hair care products | | |
| Conditioners (1249) | 1 | 0.2 |
| Rinses (47) | 1 | — |
| Shampoos (1403) | 1 | — |
| Tonics, dressings, etc (1097) | 1 | — |
| Makeup | | |
| Other (406) | 1 | — |
| Personal hygiene products | | |
| Other (514) | 1 | — |
| Skin care products | | |
| Cleansing creams, lotions, liquids, and pads (1368) | 6 | 3 |
| Face and neck creams, lotions, powders, and sprays (1195) | 5 | 7 |
| Body and hand creams, lotions, powders, and sprays (1513) | 2 | 25 |
| Moisturizers (2039) | 10 | — |
| Other (1244) | 2 | — |
| Suntan products | | |
| Indoor tanning preparations (200) | 1 | — |
| Total uses/ranges for Corn Germ Oil | 37 | 0.2-25 |
| Zea Mays (Corn) Oil | | |
| Baby products | | |
| Lotions, oils, powders, and creams (132) | 5 | 0.004 |
| Other (138) | 3 | — |
| Bath products | | |
| Soaps and detergents (1329) | 5 | 0.005 |
| Bubble bath (262) | — | 0.01 |
| Other (239) | — | 0.001 |
| Eye makeup | | |
| Eyebrow pencils (147) | 1 | — |

(continued)

Table 4. (continued)

| Product Category (FDA 2008 Totals) | 2007 Uses (FDA 2007) ¹² | Use Concentration % (2006 ^a) ¹³ |
|---|------------------------------------|--|
| Eyeliners (684) | 14 | 0.2 |
| Eye shadow (1196) | 6 | 0.07-0.1 |
| Eye lotions (177) | 8 | 0.09 |
| Eye makeup remover (131) | 4 | 0.07 |
| Mascara (463) | 1 | 0.0008 |
| Other (288) | 5 | 0.02 |
| Fragrance products | | |
| Colognes and toilet waters (1288) | — | 0.001-0.01 |
| Powders (278) | — | 0.1 |
| Noncoloring hair care products | | |
| Conditioners (1249) | 10 | 0.0003-0.02 |
| Sprays/aerosol fixatives (371) | 1 | 0.005 |
| Rinses (47) | 1 | — |
| Shampoos (1403) | 11 | 0.0001-0.04 |
| Tonics, dressings, etc (1097) | 10 | 0.004 |
| Other (716) | 5 | 0.02 |
| Hair coloring products | | |
| Dyes and colors (2481) | 178 | 0.007 |
| Tints (58) | 1 | — |
| Coloring rinses (43) | 1 | — |
| Lighteners with color (22) | 1 | — |
| Other (166) | 1 | 0.004 |
| Makeup | | |
| Blushers (539) | 7 | 0.01-0.1 |
| Face powders (613) | 12 | 0.02-0.1 |
| Foundations (635) | 6 | 0.0004-0.3 |
| Lipsticks (1912) | 29 | 0.003-10 |
| Makeup bases (164) | 1 | 0.03-0.1 |
| Makeup fixatives (38) | — | 0.1 |
| Other (406) | 4 | 0.01-0.2 |
| Nail care products | | |
| Cuticle softeners (18) | — | 0.001-5 |
| Creams and lotions (17) | — | 0.02 |
| Nail polishes and enamels (419) | — | 0.04 |
| Other (124) | 1 | — |
| Personal hygiene products | | |
| Underarm deodorants (540) | 1 | — |
| Other (514) | 2 | 0.004-0.01 |
| Shaving products | | |
| Aftershave lotions (395) | 2 | 0.02 |
| Mens talcum (7) | — | 10 |
| Preshave lotions (27) | — | 10 |
| Other (107) | 1 | 10 |
| Skin care products | | |
| Cleansing creams, lotions, liquids, and pads (1368) | 17 | 0.008-14 |
| Depilatories (62) | — | 0.1-14 |
| Face and neck creams, lotions, powders (1195) | 26 | 0.002-14 ^b |
| Body and hand creams, lotions, powders (1513) | 31 | 0.00003-14 ^b |
| Foot powders and sprays (48) | — | 0.0001-14 |
| Moisturizers (2039) | 46 | 0.00003-14 ^b |
| Night creams, lotion, and powders (343) | 5 | 0.001-14 ^b |
| Paste masks/mud packs (418) | 5 | 0.1-14 |
| Fresheners (285) | — | 0.1-14 |
| Other (1244) | 24 | 0.01-14 |
| Suntan products | | |
| Suntan gels, creams, liquids, and sprays (156) | 3 | 0.003-0.01 |
| Indoor tanning preparations (200) | 2 | 0.002-0.04 |
| Other (62) | 1 | 0.01 |
| Total uses/ranges for Corn Oil | 498 | 0.00003-14 |

(continued)

Table 4. (continued)

| Product Category (FDA 2008 Totals) | 2007 Uses (FDA 2007) ¹² | Use Concentration %(2006 ^a) ¹³ |
|--|------------------------------------|---|
| Zea Mays (Corn) Oil Unsaponifiables | | |
| Skin care products | | |
| Cleansing creams, lotions, liquids, and pads (1009) | 1 | — |
| Body and hand creams, lotions, powders, and sprays (992) | 1 | — |
| Moisturizers (1200) | 1 | — |
| Night creams, lotions, powders, and sprays () | 1 | — |
| Other (1244) | 3 | — |
| Total uses/ranges for Corn Oil Unsaponifiables | 7 | — |
| Zea Mays (Corn) Gluten Protein | | |
| Eye makeup | | |
| Eye Shadow (1196) | 1 | 0.1 |
| Makeup | | |
| Blushers (539) | — | 0.03 |
| Noncoloring hair care products | | |
| Shampoos (1403) | 3 | — |
| Total uses/ranges for Corn Gluten Protein | 4 | 0.03-0.1 |
| Zea Mays (Corn) Kernel Extract | | |
| Bath products | | |
| Other (239) | 1 | 0.00001 |
| Eye Makeup | | |
| Eye Lotions (177) | — | 0.01 |
| Makeup | | |
| Face powders 613() | — | 0.3 |
| Foundations (635) | 1 | 0.03-0.05 |
| Makeup Bases (164) | — | 0.005 |
| Other (406) | 1 | — |
| Noncoloring hair care products | | |
| Conditioners (1249) | 1 | — |
| Shampoos (1403) | 1 | — |
| Shaving products | | |
| Other (107) | 2 | — |
| Skin care products | | |
| Cleansing creams, lotions, liquids, and pads (1368) | — | 0.0001 |
| Face and neck creams, lotions, and powders (1195) | 151 | 0.01-0.1 |
| Body and hand creams, lotions, and powders (1513) | | 0.00001-0.5 |
| Moisturizers (2039) | 3 | 0.006-0.01 |
| Night creams, lotions, and powders (343) | 3 | 0.03-0.07 |
| Paste masks/mud packs (418) | 1 | 0.001 |
| Lip cream | — | 0.08 |
| Other (1244) | 5 | 0.02-0.1 |
| Suntan products | | |
| Suntan gels, creams, liquids and sprays(156) | — | 0.05 |
| Total uses/ranges for corn Kernel extract | 35 | 0.00001-0.5 |
| Hydrolyzed corn starch | | |
| Bath products | | |
| Bubble bath (262) | 1 | — |
| Eye makeup | | |
| Mascara (463) | 4 | 1 |
| Lipstick (1912) | — | 0.8 |
| Other (288) | 1 | — |
| Noncoloring hair care products | | |
| Tonics, dressings, etc (1097) | 2 | — |
| Personal hygiene products | | |
| Underarm deodorants (540) | — | 0.8 |
| Shaving products | | |
| Aftershave lotions (395) | 1 | — |
| Skin care products | | |

(continued)

Table 4. (continued)

| Product Category (FDA 2008 Totals) | 2007 Uses (FDA 2007) ¹² | Use Concentration %(2006 ^a) ¹³ |
|---|------------------------------------|---|
| Face and neck creams, lotions, and powders (1195) | 1 | — |
| Moisturizers (2039) | 1 | — |
| Fresheners (285) | 1 | — |
| Total uses/ranges for hydrolyzed corn starch | 12 | — |
| Hydrolyzed corn protein | | |
| Eye makeup | | |
| Eyeliner (684) | — | 0.1 |
| Eye lotion (177) | — | 0.004 |
| Mascara (463) | 2 | 0.1 |
| Noncoloring hair care products | | |
| Conditioners (1249) | 6 | 0.4 |
| Sprays/aerosol fixatives (371) | 2 | — |
| Shampoos (1403) | 5 | 0.09 |
| Tonics, dressings, etc (1097) | 1 | 0.008 |
| Hair coloring products | | |
| Tints (58) | — | 2 |
| Skin care products | | |
| Face and neck creams, lotions, and powders (1195) | — | 0.004 |
| Moisturizers (2039) | — | 0.01 |
| Other (1244) | 1 | 0.04 |
| Total uses/ranges for hydrolyzed corn protein | 17 | — |
| Zea Mays (Corn) seed flour | | |
| Noncoloring hair care products | | |
| Tonics, dressings, etc (1097) | 1 | — |
| Skin care products | | |
| Paste masks/mud packs (418) | 2 | — |
| Total uses/ranges for Corn Seed Flour | 3 | — |
| Zea Mays (Corn) Kernel Meal | | |
| Skin care products | | |
| Cleansing creams, lotions, liquids, and pads (1368) | 9 | — |
| Other (1244) | 2 | — |
| Total uses/ranges for corn Kernel meal | 11 | — |
| Zea Mays (Corn) silk extract | | |
| Makeup | | |
| Face powders (613) | — | 0.1 |
| Foundations (635) | — | 0.1 |
| Skin care products | | |
| Face and neck creams, lotions, and powders (1195) | — | 0.1 |
| Total uses/ranges for corn silk extract | — | 0.1 |
| Zea Mays (Corn) starch | | |
| Baby products | | |
| Lotions, oils, powders, and creams (132) | 12 | 98-99 |
| Bath products | | |
| Oils, tablets, salts, etc (257) | 3 | — |
| Soaps and detergents (1329) | 2 | 0.01-0.4 |
| Other (239) | 2 | — |
| Eye makeup | | |
| Eyeliner (684) | 1 | 3 |
| Eye shadow (1196) | 29 | 1-8 |
| Eye lotion (177) | 1 | — |
| Mascara (463) | — | 0.1 |
| Other (288) | 3 | 0.2 |
| Fragrances | | |
| Colognes and toilet waters (1288) | — | 14 |
| Perfumes (569) | — | 14-34 |
| Powders (278) | 23 | 14-80 |
| Sachets (28) | — | 14 |
| Other (399) | — | 14 |

(continued)

Table 4. (continued)

| Product Category (FDA 2008 Totals) | 2007 Uses (FDA 2007) ¹² | Use Concentration %(2006 ^a) ¹³ |
|---|------------------------------------|---|
| Noncoloring hair care products | | |
| Conditioners (1249) | 3 | 2 |
| Sprays/aerosol fixatives (371) | — | 0.00002 |
| Tonics, dresings, etc (1097) | — | 0.00002-0.5 |
| Hair coloring products | | |
| Bleaches (152) | — | 6 ^c |
| Makeup | | |
| Blushers (539) | 28 | 0.005-14 |
| Face powders (613) | 43 | 0.9-27 |
| Foundations (635) | 3 | 0.7-14 |
| Lipsticks (1912) | 19 | 1-5 |
| Makeup bases (164) | — | 14 |
| Rouges (99) | — | 12 |
| Makeup fixatives (38) | — | 14 |
| Other (406) | 8 | 2-15 |
| Oral hygiene products | | |
| Dentifrices (59) | — | 25 |
| Personal hygiene products | | |
| Underarm deodorants (540) | 6 | 0.01-2 |
| Douches (12) | — | 0.01 |
| Feminine deodorants (21) | 5 | 0.01-25 |
| Other (514) | 7 | 0.01-97 |
| Shaving products | | |
| Aftershave lotions (395) | — | 10 |
| Beard softeners (0) | — | 10 |
| Preshave lotions (27) | 1 | — |
| Shaving creams, gels, etc (162) | 1 | 0.8 |
| Other (107) | 2 | — |
| Skin care products | | |
| Cleansing creams, lotions, liquids, and pads (1368) | 8 | 5-20 |
| Depilatories (62) | — | 5 |
| Face and neck creams, lotions, powders (1195) | 18 | 8 |
| Body and hand creams, lotions, powders (1513) | 9 | 1-45 |
| Foot powders and sprays (48) | 6 | 25-65 |
| Moisturizers (2039) | 21 | 0.7-2 |
| Night creams, lotion, and powders (343) | 2 | 1 |
| Paste masks/mud packs (418) | 6 | 0.7-5 |
| Other (1244) | 5 | 2-98 ^d |
| Suntan products | | |
| Indoor tanning preparations (200) | 1 | 5 |
| Total uses/ranges for corn starch | 278 | 0.00002-99 |

^a No changes in use concentration were reported in 2007 or 2008.

^b The concentration range specifically for sprays in this category was 0.1% to 14%

^c 2% After dilution

^d 98% In a wax epilation product

Dermal Sensitization

Magnusson and Kligman Maximization tests using corn kernel extract were conducted on 30 albino guinea pigs (300–350 g).¹⁷ The scapular area of 15 animals was injected with 0.1 mL 50% Freund adjuvant in 0.9% isotonic NaCl solution, 0.1 mL of corn kernel extract, and a 0.1 mL mixture of equal parts Freund adjuvant and corn kernel extract. Six days later, 1 mL of a 10% lauryl sodium sulfate solution was applied. Twenty-four hours later, 0.5 mL of pure corn kernel extract was applied under a semi-occlusive dressing for 48 hours. The remaining 15 animals

underwent the same procedure, replacing corn kernel extract with physiological serum. All of the animals were allowed to rest for 2 weeks. On all the animals, 0.5 mL of corn kernel extract was then applied under a semi-occlusive dressing for 24 hours on the dorsal regions and 0.5 mL on the rear area of the back. No macroscopic reactions were observed in any animals.

Corn Oil as a Vehicle/Control

Corn oil frequently has been used as a vehicle/control in studies of a wide range of endpoints in which another chemical (or

several other chemicals) was actually the subject of the study. These endpoints include neuron apoptosis behavior, blood pressure, metabolism, body core temperature, enzyme activity, flash evoked potentials hair growth, hormone levels, immune response, seizures, learning ability, pulmonary damage, motor functions, and T cell effects.¹⁸⁻⁶⁶

Other studies addressed acute, short-term, subchronic, and chronic animal toxicity endpoints.⁶⁷⁻⁸²

Other studies particularly addressed hepatotoxicity, nephrotoxicity, neurotoxicity, Clara cell cytotoxicity, and ototoxicity.^{74,77,83-112}

Corn oil also has been used as a delivery vehicle and control in developmental toxicity studies, reproductive toxicity studies, sperm toxicity studies.¹¹³⁻¹⁵⁶

Corn oil has been used as a vehicle in gene expression studies, a DNA adduct study, a mutagenicity study, and anti-genotoxicity studies.^{95,157-163}

These studies were carried out using rats, mice, hamsters, guinea pigs, rabbits, ferrets, sheep, pigs, cows, and monkeys. The bulk of the information in these studies concerns the tested chemicals, but, despite the wide range of endpoints studied and animal species used, in none of the studies was corn oil found to have an effect when evaluated as a vehicle/control.

Reproductive and Developmental Toxicity

The reproductive toxicity of corn oil was examined.¹⁶⁴ Seven-week-old female Sprague-Dawley rats were fed either an animal protein-based diet (CA-1) or a plant-based protein diet (CE-2). These animals were mated with a male on the same diet. The rats received 2 or 10 mL corn oil/kg body weight daily by gavage during a 2-week premating period. After mating, pregnant females were weighed and their food consumption reduced on days 0, 7, 14, and 20 of gestation. Dams were weighed and food consumption recorded on days 0 and 4 of lactation. All females were exsanguinated under pentobarbital anesthesia on day 4 of lactation, and the uteri, ovaries, kidneys, livers, and thymuses examined. All pups were euthanized and necropsied on day 4 of lactation.

Dams fed the CA-1 diet and receiving 10 mL/kg corn oil demonstrated soiled fur, hunchback position, piloerection, hypothermia, and decrease in movement. Untreated dams and those on 2 mL/kg corn oil did not show any clinical abnormalities nor did any rats on the CE-2 diet. Both CA-1 and CE-2 rats receiving 10 mL/kg corn oil had significant decreases in food consumption and body weight gain. On day 4 of lactation, there was a significant decrease in the number of pups surviving from the CA-1 dams on 10 mL/kg corn oil. Autopsy of adult females fed the CA-1 diet and 10 mL/kg corn oil revealed some pale and dark-colored kidneys, small thymus, small spleen, erosion in the stomach, and soiled fur. These rats also showed severe epithelial necrosis and fatty degeneration of the proximal tubule.¹⁶⁴ The author suggested 10 mL/kg of corn oil gavage as a vehicle can be a confounding effect in pregnant rats.

Genotoxicity

The effect of corn oil in the diet on mammary gland mutations was examined using female Big Blue rats treated with either 75 mg/kg of 2-amino-1-methyl-6-phenylimidazo[4,5-b]pyridine (PhIP) or 125 mg/kg of 7,12-dimethylbenz[a]anthracene (DMBA).¹⁶⁵ Rats were assigned to either a high-fat (23.5% corn oil) or low-fat (5% corn oil) diet. For each carcinogen, a control group was given the identical volume (5 mL/kg) and dosage regimen of corn oil vehicle. PhIP was administered by oral gavage at 75 mg/kg mixed in corn oil. Ten doses were administered for 5 consecutive days, followed by 2 days without dosing, followed by another 5 days of dosing. DMBA was given as a single gavage dose of 124 mg/kg in corn oil at 50 days of age. The experiment duration was 6 weeks, which was sufficient for the expression of mammary gland mutations. Rats were killed and abdominal mammary glands and liver were examined. The level of corn oil in the diet had no effect.

Carcinogenicity

The link of a high-fat diet to cancer has been studied for mammary; colon; lung; liver; pancreatic; prostate; and intestinal cancer.¹⁶⁶⁻¹⁷² While a link to increased cancer incidence was found for some sites and not others, these studies were not considered relevant to the assessment of corn-derived ingredients in concentrations as used in cosmetics.

NTP studied the use of corn oil, safflower oil, and tricaprylin as gavage vehicles.¹⁷³ Groups of 50 male F344/N rats were administered 2.5, 5, or 10 mL/kg of each tested vehicle, or 10 mL/kg saline, by gavage for 5 d/week for 2y. Saline-treated animals served as controls. Corn oil, safflower oil, and tricaprylin each caused hyperplasia and adenoma of the exocrine pancreas, decreased incidences of mononuclear cell leukemia (MNCL), and reduced incidences/severity of nephropathy. The authors concluded that the use of corn oil as a gavage vehicle may have a confounding effect on the interpretation chemical induced proliferative lesions of the exocrine pancreas and MNCL.

Clinical Assessment of Safety

Dermal Sensitization/Irritation

Corn kernel extract. The contact-sensitization potential of a face cream containing 1% of a 3% corn kernel extract was evaluated in human skin by maximization assay on 27 adult volunteers (25 females, 2 males; ages 19-57).¹⁷⁴ Following pretreatment by 0.05 mL sodium laurel sulfate (SLS; 0.25%) for 24 hours, 0.05 mL of the test material was applied and occluded for 48 to 72 hours in 5 separate induction exposures. After a 10-day rest period, SLS pretreatment occurred, followed by challenge with 0.05mL of the test material.

One female participant dropped out of the study for unknown reasons. There were no instances of allergic reaction or sensitization 48 or 72 hours after application of challenge patches.

The skin tolerance of corn kernel extract, diluted at 10%, was tested on 21 participants (15 females, 6 males) using a single patch test.¹⁷⁵ The patch test utilized Finn Chambers on Scanpor tape with an area of 50 mm² and a 20 µL capacity. These were applied to the scapular area of the volunteers and covered with an adhesive; control patch tests with no product were conducted concurrently. The patches were removed 48 hours after application and evaluated for irritation after 30 minutes. Light erythema was observed in 1 male volunteer. There was no reaction in any other participants.

Corn starch. A repeated insult patch test (RIPT) was done on 99 participants (26 male 73 female, ages 18-70) using feminine powder containing 97% corn starch.¹⁷⁶ A patch was applied for 24 hours, after which it was removed. The same area was then repatched either 24 or 48 hours after the removal. This was repeated until 9 induction patchings were completed. Approximately 2 weeks after induction patching, a challenge patch was placed on a new site and then removed after 24 hours. The induction and challenge sites were observed at 48, 72, and 96 hours after the removal of the challenge patch. Four cases of faint, minimal erythema were observed during the induction phase, and there was no observed irritation during the challenge phase. This same methodology was repeated with 109 participants (35 male 74 female, age 18-68) completing the study. There was no observed irritation in the participants.

Corn gluten protein. A RIPT was done on 51 volunteers (43 female, 8 male) of phototypes I to IV using corn gluten protein.¹⁷⁷ A mixture of mineral oil (95%) and corn gluten protein (5%) was prepared and 0.05 g/cm² was applied to a patch. The patch was then applied to the right or left side of the backs of the participants and covered with semi-occlusive hypoallergenic tape. The patch was removed 48 hours later and reactions recorded after 30 minutes and 24 hours. Applications were performed daily to the same site over the course of 3 weeks, after the first application had been in place for 48 or 72 hours. After 14 consecutive applications, none were applied for a period of 2 weeks. Afterward, a single patch with the sample was applied to a virgin area. After 48 hours, the patch was removed and reactions recorded after 30 minutes and 24 hours. No adverse reactions were detected at the test sites for either primary or cumulative irritation and/or sensitization.

A study was done in which 94 participants (85 female, 9 male) completed an allergic contact sensitization test to eye shadow containing 12.6% of 1% corn gluten protein.¹⁷⁸ Ten patches were applied to the upper backs of the participants after 0.1 g of the test material was added. The patches were applied for 24 hours, 3 days/week for 3 wks to the same sites. During week 6, a single patch of the material was applied to a virgin site for 24 hours and then scored 24 and 48 hours after removal. There was no evidence of any effect from the patches.

Using the same method as above, an eye shadow containing 10.0% of 1% corn gluten protein was tested for allergic contact sensitization in 85 participants (82 female, 3 male).¹⁷⁹ Three participants exhibited minimal faint uniform or spotty

erythema and 1 exhibited bright red erythema with accompanying edema, petechiae, or papules. There were no other reported effects.

Corn silk extract. A RIPT was done on 56 participants (ages 20-79; 44 female, 12 male) using a powder containing 0.1% corn silk extract. Five participants did not complete the study for reasons unrelated to the test materials.¹⁸⁰ Approximately 0.2 g of the test material was applied as an occluded patch and applied to the upper back between the scapulae. Patches were applied 3 times a week for a total of 9 applications lasting 24 hours each with 24 or 48 hours between them. If any site exhibited a moderate reaction during this phase, the application was moved to an adjacent area. If the new site exhibited a moderate reaction, the applications were discontinued. Two weeks after the initial application, a challenge patch was applied to a site adjacent to the induction patch site. After the patch was removed, the site was scored 24 and 72 hours after removal. None of the participants exhibited any visible skin reaction.

An RIPT was done on 112 participants (ages 19-79; 83 female, 29 male) using a powder containing 0.1% corn silk extract.¹⁸¹ Six participants did not complete the study for reasons unrelated to the test materials. The same procedure as above was used. There were no visible skin reactions among the participants.

An RIPT was done on 57 participants (ages 16-79; 46 female, 16 male) using a powder containing 0.1% Corn Silk Extract.¹⁸² Six subjects did not complete the study for reasons unrelated to the test materials. The same procedure as above was used. There were no visible skin reactions among the subjects.

Twenty subjects (ages 21-45; 17 female, 3 male) with an active case or a history of acne vulgaris to a human comedogenicity test were tested with a powder composite containing 0.1% corn silk extract.¹⁸³ Sites on the upper back were wiped with 70% isopropyl alcohol, and approximately 0.2 g of the test material was applied onto an occlusive patch and affixed to the skin. An untreated patch was also applied as a negative control. Three days a week for 4 consecutive weeks, patches were removed and the sites evaluated for irritation. Fresh patches were applied afterward. At the final session, sites were cleansed with 70% isopropyl alcohol and patted dry. Follicular biopsies were taken from these sites and the specimens were evaluated by the ratio of microcomedones to follicles per visual field. There were no cases of dermal irritation. The follicular biopsy evaluation resulted in a microcomedones: follicle ratio of 0 for 18 participants, 0.6 in 1 participant, and 0.7 in 1 participant.

An RIPT was done on 55 participants (ages 22-69; 44 female, 11 male) using a powder containing 0.1% corn silk extract.¹⁸⁴ Two participants did not complete the study for reasons unrelated to the test materials. Before application to the upper back between the scapulae, the area was wiped with 70% isopropyl alcohol and allowed to dry. Once applied, a semi-occlusive patch with test material was in direct contact with the skin for 24 hours. Patches were applied 3 times a week for a total of 9 applications and evaluated 24 or 48 hours after

removal. After a 2-week rest period, challenge patches were applied to untreated sites on the back and left for 24 hours. The sites were evaluated at removal and reevaluated at 48 and 72 hours. Four participants exhibited a barely perceptible erythema at the first induction. There were no other visible skin reactions.

An RIPTS was done on 55 participants (ages 22-69; 44 female, 11 male) using a powder containing 0.1% corn silk extract.¹⁸⁵ Two participants did not complete the study for reasons unrelated to the test materials. The RIPT was performed as above. Three participants exhibited a barely perceptible erythema at the first induction. There were no other visible skin reactions.

Case Reports

Corn starch. Several reports of hypersensitivity to cornstarch used as a powder in medical gloves were reported.¹⁸⁶⁻¹⁹¹ One case report of a granuloma following laparoscopic surgery in which powered gloves were used.¹⁸⁹ Silver et al reported an instance of respiratory failure in an infant who had aspirated corn starch during a diaper change.¹⁹²

Summary

Corn Cob Meal is the milled powder prepared from the cobs of *Zea mays*. In cosmetics, it functions as an abrasive and bulking agent and is used at 3%.

Corn cob powder is the powder obtained from the dried ground cobs of *Zea mays*. It functions as an abrasive and is used at 0.7% to 10%.

Corn fruit is the fruit of *Zea mays*. This ingredient is currently not in use.

Corn germ extract is an extract of the germ of the corn, *Zea mays*. It is currently reported to be used, but at an unknown concentration.

Corn germ oil is the oil obtained from the germ of *Zea mays*. It functions as an occlusive skin conditioning agent and is used at 25%.

Corn gluten protein is a protein obtained from the starchy endosperm of corn, *Zea mays*. It functions as a bulking agent, hair conditioning agent, and skin conditioning agent and is used at up to 0.1%.

Corn kernel extract is an extract of the kernels of corn, *Zea mays*. It is used at 0.5%.

Corn kernel meal is the coarse flour prepared by milling the kernels of *Zea mays*. It is used as an abrasive and a bulking agent used at 3%.

Corn oil is the refined fixed oil obtained from the wet milling of corn *Zea mays*. It is a mixture of the following fatty acids: myristic, palmitic, stearic, hexadecenoic, oleic, and linoleic. Corn oil functions as a fragrance ingredient, hair conditioning agent, occlusive skin conditioning agent, surfactant, and emulsifying agent and is used at concentrations up to 14%.

Corn oil unsaponifiables is the fraction of corn oil (qv) which is not saponified in the refining recovery of corn oil fatty

acids. It functions as a hair conditioning agent, and skin conditioning agent. Although reportedly in current use, the concentration is unknown.

Corn seed flour is the powder prepared from the fine grinding of the inner portion of the seeds of *Zea mays*. It is used as an abrasive, absorbent, binder, and bulking agent. Although reportedly in current use, the concentration is unknown.

Corn silk extract is an extract of the stigmas of the corn, *Zea mays* used at 0.1%.

Corn starch is a starch obtained from corn, *Zea mays*. Corn starch is composed of amylose and amylopectin. It functions as an abrasive, absorbent, skin protectant, and a viscosity increasing agent and is used at concentrations up to 99%.

Hydrolyzed corn starch is the hydrolysate of corn starch (qv) derived by acid, enzyme, or other method of hydrolysis. It functions as a skin conditioning agent and is used at concentrations of 0.8% to 1%.

Hydrolyzed corn protein is hydrolysate of corn protein derived by acid, enzyme, or other method of hydrolysis. It functions as a hair conditioning agent and skin conditioning agent and is used at concentrations up to 2%.

Corn kernel extract was tested for ocular irritation, oral toxicity, and dermal sensitization. Slight eye irritation in rabbits occurred within a day of application, but all symptoms disappeared after 24 hours. Maximization tests performed on guinea pigs did not produce any observed dermal irritation. Oral toxicity in rats was tested, producing no signs of toxicity. One clinical test of corn kernel extract as a skin irritant produced light erythema in a single volunteer (n = 21), but no other signs of irritation. Corn kernel extract was also negative in 27 individuals in a maximization test.

There were no safety test data available for corn acid, potassium cornate, or corn glycerides.

Corn oil is commonly used as a vehicle in studies of lipid-soluble substances. These studies were carried out using rats, mice, hamsters, guinea pigs, rabbits, ferrets, sheep, pigs, cows, and monkeys. The bulk of the information in these studies concerns the tested chemicals, but, despite the wide range of endpoints studied and animal species used, in none of the studies was corn oil found to have an effect when evaluated as a vehicle/control.

When rats were fed different types of diets, those fed hydrolyzed corn starch had greater carbohydrate intake, total food intake, and body weight gain compared to those fed amylopectin. The same was true with the gel forms of the different carbohydrates as diets. The life spans of rats fed high-phytosterol oils, including corn oil, were significantly shorter than those fed a fat blend or soybean oil. Carcinogenesis studies in which the effect of corn oil in high-fat diets was examined and found to increase the likelihood of several, but not all, cancer types. These dietary studies, however, were not considered relevant to assessing the safety of corn oil at concentrations used in cosmetics.

There was 1 case report of respiratory distress in an infant that inhaled corn starch during a diaper change. There are several cases on granulomas and urticaria caused by the corn starch on latex gloves. Cases were usually of patients being treated by gloved personnel or hospital personnel themselves developing reactions. Eye shadow formulations tested in repeat insult patch tests containing corn gluten protein produced irritation in 3 of 85 participants, but no allergic reactions.

Discussion

The CIR Expert Panel found that the information provided is sufficient to identify the following ingredients as safe as used: Zea Mays (Corn) oil; Zea Mays (Corn) cob meal, Zea Mays (Corn) cob powder, Zea Mays (Corn) fruit, Zea Mays (Corn) germ extract, Zea Mays (Corn) germ oil, Zea Mays (Corn) gluten protein, Zea Mays (Corn) kernel extract, Zea Mays (Corn) kernel meal, Zea Mays (Corn) oil unsaponifiables, Zea Mays (Corn) seed flour, Zea Mays (Corn) silk extract, Zea Mays (Corn) starch; corn acid, corn glycerides, hydrolyzed corn protein, hydrolyzed corn starch, and potassium cornate.

Although there are not safety test data available on all of these ingredients, the Panel has considered that the chemical characterization of each ingredient for which data are available is sufficient to apply those available data to ingredients with similar composition.

Also relevant is the long history of use of corn oil as a vehicle/control in studies of other chemicals. While it is the intent that a vehicle will itself have no effect, the Panel reviewed studies that addressed a large number of different endpoints that were unaffected by corn oil as a vehicle. These included behavioral studies; acute, short-term, subchronic, and chronic toxicity studies; reproductive and developmental toxicity studies; and genotoxicity studies.

There were numerous carcinogenicity studies in which the effect of corn oil in high-fat diets was examined, but these data were not considered relevant to assessing the safety of these ingredients at concentrations used in cosmetics.

The CIR Expert Panel recognizes that there are data gaps regarding use and concentration of these ingredients. However, the overall information available on the types of products in which these ingredients are used and at what concentrations indicate a pattern of use, which was considered by the Expert Panel in assessing safety.

The Expert Panel expressed concern regarding pesticide residues and heavy metals that may be present in botanical ingredients. They stressed that the cosmetics industry should continue to use the necessary procedures to limit these impurities in the ingredient before blending into cosmetic formulation.

Concern was expressed about alternative approaches to extraction that might not produce material with the same safety profile described in this safety assessment, especially if pesticides were used on the plants. While extracts from pesticide-free plants were not genotoxic and there do not appear to be any

components that could be carcinogenic, pesticide residues could raise this issue. The Panel urged that manufacturers limit pesticide residues to the limit previously used for lanolin of not more than 40 ppm (with not more than 10 ppm for any 1 residue). Extracts not prepared in a manner that produces a similar chemical profile would be considered safe if they have a similar safety test profile.

Conclusion

The CIR Expert Panel concludes that the following ingredients are safe as used as described in this report: Zea Mays (corn) oil; and Zea Mays (corn) cob meal, Zea Mays (corn) cob powder, Zea Mays (Corn) fruit, Zea Mays (corn) germ extract, Zea Mays (corn) germ oil, Zea Mays (corn) gluten protein, Zea Mays (corn) kernel extract, Zea Mays (corn) kernel meal, Zea Mays (corn) oil unsaponifiables, Zea Mays (corn) seed flour, Zea Mays (corn) silk extract, and Zea Mays (corn) starch; and corn acid, corn glycerides, hydrolyzed corn protein, hydrolyzed corn starch, and potassium cornate. Were ingredients in this group not in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in the group.

Author's Note

Unpublished sources cited in this report are available from the Director, Cosmetic Ingredient Review, 1101 17th St., Suite 412, Washington, DC 20036, USA.

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