FINAL REPORT OF THE SAFETY ASSESSMENT FOR WHEAT FLOUR AND WHEAT STARCH

Wheat Flour, a natural product obtained from wheat grain, consists primarily of starch and gluten fractions. These ingredients are not toxic when administered orally. Dermatologic studies show these ingredients to be nonirritating and nonsensitizing.

Studies of allergic respiratory disorders caused by chronic inhalation of Wheat Flour dust are numerous, but the cosmetic use of this ingredient does not provide the conditions under which such sensitization is likely to occur.

Wheat Flour and Wheat Starch are safe as cosmetic ingredients in the present practices of use and concentration.

CHEMICAL AND PHYSICAL PROPERTIES

Preparation, Composition and Physical Characteristics

Wheat Flour Wheat Flour is the milled flour grain endosperm. It is a fine, soft powder that contains 70-75% carbohydrates, 9.5 - 13.5% protein (%N x 5.7), and approximately 12% moisture (CTFA, 1978a)[1].

The principal constituents of flour are starch and gluten, and their proportion varies greatly in different wheat varieties grown under different climatic conditions. The extremes have been reported to be, roughly, from 17% gluten and 70% starch to 6% gluten and 81% starch (Brother and Olcott, 1947).

The inorganic constituents of Wheat Flour are (in descending order): K(0.571%), P, S, Mg, Cl, Ca, Na, Si(0.006%). The elements Zn, Fe, Mn, B, Cu, and Al are present in concentrations no greater than 100 ppm (Sullivan, 1933).

There is abundant literature concerning the chemical and physical characteristics of Wheat Flour and its components (Agatova and Proskuryakov, 1962; Bietz and Wall, 1972; Bourdet, 1956; Boutaric and Fabry, 1945; Bungenberg de Jong and Klaar, 1929; Colvin and McCalla, 1949; DeRege, 1935; Dimler and Senti, 1959; Godon and Petit, 1967; Gortner, 1931; Grosskreutz 1961; Haex, 1962; Hoseney *et al.*, 1969; Howe, 1946; Hussein, 1961; Jones, 1961; Juvrud, 1927; Kaczkowski, 1965; Kimura, 1956; Lasztity, 1970; Laws and France, 1949; Lorenz and Maga, 1975; The Merck Index, 1976; Oh *et al.*, 1966; Pence *et al.*, 1950; Ponte *et al.*, 1967, Pradac, 1959; Prischep *et al.*, 1974a, b; Rohrlich, 1973; Sandstedt and Mattern, 1958; Stockelbach and Bailey, 1938; Wagner, 1948; Yakobenko and Litvinov, 1975).

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[1]Available upon request. Administrator, Cosmetic Ingredient Review, Suite 212, 1133 15th St., NW, Washington, DC 20005

Wheat Starch Wheat Starch is the amylose and amylopectin-rich portion of Wheat Flour. It consists of 86-91% carbohydrates and 9-13% moisture (CTFA, 1978b).

Starch, a polymer of glucose, is the carbohydrate reserve of plants. Native starch occurs in minute granules varying in size and shape depending on the plant source. Starch molecules in the granule are held together by hydrogen bonding (Paschall 1974; Wurzburg, 1972).

The linear polymer amylose contains about 200 to 2,000 D-anhydroglucose units joined by alpha-1,4 bonds. The branched polymer amylopectin consists of linear alpha-1,4 linked segments branched through alpha-1,6 bonds at 15 to 25 anhydroglucose unit intervals (Paschall 1974; Wurzburg, 1972).

Wheat Starch is produced commercially by wet-milling processes in which the starch is liberated by grinding aqueous slurries of wheat grain. It is then refined, filtered, and dried. Sulfur dioxide is used to aid in the separation of starch from the protein matrix of wheat grain (Watson, 1967).

Reactivity

Wheat Flour Wheat flour contains no solvents or diluents (CTFA, 1978a). The water binding capacity of wheat flour is inversely related to pH and is not affected by iodate, N-ethylmaleimide, or sulfite, which affect the -SH -S-S system of flour proteins (Bushuk, 1963).

Flour proteins do not include papainases as formerly believed. The natural proteolytic enzymes of flour have marked effects on other proteins but have little, or no, action on flour proteins (Sandstedt and Mattern, 1958).

Wheat Starch Information is available regarding the many chemical treatments used in making modified starches as food ingredients (FASEB, 1977).

The water binding capacity of Wheat Starch is independent of pH (Bushuk, 1963.)

Gelatinization of Wheat Starch occurs with baking. This involves an irreversible crystallization of amylose. Parallelization of the amylose polymers and consequent association through hydrogen bonding occurs. The amylopectin fraction crystallizes slowly after cooling. This coacervation continues for several days (Wurzburg, 1972; Osman, 1967).

Amylose has an affinity for iodine, fatty acids, various surfactants, and other large molecules with hydrophobic and hydrophylic sections (Wurzburg, 1972).

Analytical Methods

The extensive literature on analytical methods for these ingredients is derived mostly from the milling and food technology industries (Laws and France, 1949, Anonymous, 1958; Bahl *et al.*, 1976; Benatar and Weneret, 1947; Benhamou-Glynn *et al.*, 1965; Berliner and Koopman, 1929; Berliner, 1939; Chabot, 1925; Cirilli, 1969; Eeckhaut, 1956; Hertwig, 1928; Jones *et al.*, 1963; Lawellin, 1920; Lawrence *et al.*, 1970; Libby, 1970; Marinelli,

1938; Morison, 1921; Pradac and Prugar, 1961; Rottinger and Woidich, 1928; Rottinger, 1929; Simskaya, 1951; Soenen and Pinguair, 1939; Stauffer *et al.*, 1958; Terent'eva *et al.*, 1973; Trop and Grossman, 1972; Ziegler, 1942).

Impurities

Wheat Flour The CTFA Cosmetic Ingredient Chemical Description for Wheat Flour includes the following as known minor impurities (CTFA, 1978a):

Sugars	1.5 to 2.0%
Fat	1.0 to 2.0%
Fiber (Cellulose)	0.35% maximum
Ash	0.3 to 0.8%

Wheat Flour contains no solvents or diluents (CTFA, 1978a). One study detected no nitrites or nitrosamines in Wheat Flour (Thewlis, 1967).

FDA rules permit the addition of certain materials in order to improve the nutritional value of Wheat Flour. As a result, much of the commercially available Wheat Flour is "enriched" with various vitamins and minerals. These may include niacin, riboflavin, thiamine, and iron (CTFA, 1978a).

Wheat Starch The CTFA Cosmetic Ingredient Chemical Description for Wheat Starch includes the following as known minor impurities (CTFA, 1978b):

Protein (%N x 6.25)	0.50% maximum
Fiber (Cellulose)	0.25% maximum
Ash	0.20% maximum
Fat (Ether Extractable)	0.15% maximum

Wheat Starch contains no diluents, solvents, or additives. Residual sulfur dioxide may be present at a concentration not greater than 0.008% (CTFA, 1978b).

USE

Cosmetic Use

Wheat Flour is found in one cleansing preparation, and Wheat Starch in four formulations of face powders. The concentrations and the associated number of product formulations for each of these ingredients are shown in Table 1 (FDA, 1976) below. The route and frequency of application of formulations containing these ingredients can only be inferred, but it is clear that the opportunity exists for eye contact and inhalation of small amounts as well as absorption through the skin. No information was available on possible interactions with other cosmetic ingredients, although wheat flour proteins have sulfhydryl and amino groups.

TABLE 1. Product Formulation Data (FDA, 1976)

Ingredient	Cosmetic Product Type	Concentration (%)	Number of Product Formulations
Wheat Flour	Cleansing preparations (cold creams, cleansing lotions, liquids, pads)	>0.1 to 1	1
Wheat Starch	Face powders	> 10 to 25	2
		> 5 to 10	2

Wheat Starch is reported to have emollient and demulcent functions in cosmetic applications (Rinzler, 1977). It functions also as a carrier and absorbing agent in face powders.

Non-Cosmetic Use

Wheat Flour Wheat Flour has been a staple food for perhaps 10,000 years. It is currently used in breads, pastries, and pasta products and is usually baked before consumption.

Pursuant to the Food and Drug Administration, Wheat Flour is listed as a Generally Recognized as Safe (GRAS) food ingredient (21 CFR 137.105).

Wheat Starch Starch, mainly as a component of cereal products and vegetables, supplies about 20% of the energy content of the average American diet. The available food supply provides about 180 grams of starch per capita per day (Friend and Marston, 1975). In the food industry, unmodified starches are used primarily as thickening or gelling agents and processing aids. Dry granular starch is used as a diluent, bulking agent, fluidifying agent, and mold and moisture absorbing agent (Wurzburg, 1972; Osman, 1967).

Pursuant to the Food and Drug Administration, commercial Wheat Starch is listed as a Generally Recognized as Safe (GRAS) food ingredient (21 CFR 170.30(d)).

Non-food industrial applications of all unmodified starches account for another ten grams per capita per day (Russell, 1973). Gelatinized unmodified starch serves as an internal binder and sheet strengthener for paper products (Nissen, 1967). In the textile industry, starch is used primarily in the sizing of cotton yarns and is removed from most fabrics subsequent to weaving (Compton and Martin, 1967).

BIOLOGICAL PROPERTIES

General Effects

Wheat Flour is composed of a water-soluble fraction, starch (produced by water extraction), and a water-insoluble fraction, gluten (produced by water washing; not more than 17% yield). No evidence was available that suggests any biologically significant interaction between the two fractions. Thus, the

expected biological effects of Wheat Flour should be no more than the sum of the gluten and starch effects. Conversely, much of the data obtained for Wheat Starch or gluten can be logically linked to Wheat Flour.

Absorption, Metabolism, Storage and Excretion

Wheat Flour The rates and patterns of absorption of the gluten fraction of Wheat Flour across the intestinal wall in relation to celiac disease have been widely explored. Intestinal hydrolysis of gluten and absorption of the amino acids does not appear to be affected by the disease (Douglas and Booth, 1968; (1969). In addition, some research concerning the relationship between wheat exposure and fat and protein metabolisms indicates that gluten ingestion reduces liver cholesterol in the rat (Ranhotra, 1973, 1977; Ranhotra *et al.*, 1976) and decreases blood urea levels in human beings (Bolourchi, 1968).

Wheat Starch Rats have been found to absorb 23.2 g (standard deviation = 9.19) of starch per kg daily from a normal diet containing approximately 65% starch (Boyd, 1973). The intestinal absorption coefficient of starch for normal children 1-2 years old is greater than 99% (Auricchio *et al., 1967).*

Maltose, maltotriose, and alpha-limit dextrins containing five to nine glucose residues and one or more alpha-1,6 branching links are the products of alpha-amylase digestion of cooked (gelatinized) starch within the intestinal lumen. These products are then converted to glucose by an alpha-dextrinase, glucoamylase, and maltase contained in the intestinal mucosa brush border. Only glucose is transported through the intestinal wall into the bloodstream (Gray, 1975).

Animal Toxicity Studies

Acute Studies

Eye Irritation *Wheat Flour:* A mascara base containing the gluten fraction of Wheat Flour at a concentration of 1% was tested for eye irritation in rabbits by both the Draize procedure and that described in the Federal Hazardous Substances Act (CTFA, 1976). A mild circumcorneal injection was noted in 50% of the animals and a mild discharge in two animals. These changes were thought to be typical of those resulting from foreign objects in the eye and were attributed to mechanical effects of the dried mascara base. There was complete recovery within 72 hours.

Subchronic Studies

Wheat Flour It was observed in 1944 and confirmed in 1947 that wheat gluten flour at a level of 10% or higher in the diet produced "running fits" in dogs (canine hysteria) as early as three days after the start of the diet (Erickson *et al.*, 1947; Wagner and Elvehjem, 1944). Symptoms included epileptic seizures and running-barking episodes. It was subsequently shown that this disturbance was caused by a toxic factor produced by the interaction of wheat gluten with

the nitrogen trichloride used in the commerical processing of flour (Parry, 1948; Radomski *et al.*, 1948). Newell *et al.* (1948) later showed that high levels of NCl_3 treated wheat gluten in the diet are tolerated by several species of animals, including man. NCl_3 is no longer used in the processing of Wheat Flour.

Wheat Starch Wistar rats of 50 g initial body weight were fed, for 28 days, diets containing either six percent casein and 77% Wheat Starch or 15% casein and 66% Wheat Starch. The animals showed normal weight gains, protein efficiency ratios, and cecal weights (Reussner *et al.*, 1963).

A 90-day subchronic oral toxicity study was conducted with two groups of 20 rats each. One group received a diet containing 25% Wheat Starch by weight; the other was fed the basic stock diet. After 90 days, there were no significant differences in food consumption between the two groups and no differences in their hematology and urine analyses. There were no pathological findings (Hercules, 1961)

Clinical Assessment of Safety

Dermatologic Studies

Wheat Flour The Shelanski repeated insult patch test technique was used on 50 subjects to test two mascara base products each containing 1% wheat gluten. No adverse reactions occurred (CTFA, 1977a).

The Modified Draize-Shelanski repeated insult patch test technique was performed on 202 subjects using 1% wheat gluten in a mascara base. Of the 11 reactions that occurred, two were considered to be due to preservatives and nine to "non-specific irritation" (CTFA, 1977a).

One percent wheat gluten in a mascara base was worn by 50 subjects in normal usage under the supervision of a dermatologist. No objective signs of dermatitis were noted (CTFA, 1977b), but the duration of the study was not reported. During five years of use of two products containing wheat gluten, the number of reported adverse reactions was 2.0 for one product and 0.15 for the other product per 100,000 units sold. None of the reactions was attributed to wheat gluten (CTFA, 1977c).

Wheat Starch In a modified Draize repeated insult patch test performed on 23 human subjects, Wheat Starch was nonirritating and produced no sensitization (Hercules, 1959a).

Challenge reaction scores were obtained for 210 subjects in a Schwartz prophetic patch test using Wheat Starch moistened with distilled water. None of the 210 subjects exhibited signs of sensitization (Hercules, 1959b).

Ingestion Studies

Wheat Flour Herpetiformis and Celiac Disease: Dermatitis herpetiformis is a chronic, pruritic, papular-vescular eruption affecting extensor surfaces. An associated gluten-sensitive enteropathy, sometimes termed celiac disease or non-tropical sprue, occurs in approximately 65-95% of affected patients (Albot *et al.*, 1969; Allardyce and Shearman, 1975; Asquith, 1975; Auricchio, 1970;

Bataller *et al.*, 1973; Bender, 1974; Cornell and Townley, 1974; Dissanayake *et al.*, 1973; Evans and Patey, 1974; Ezeoke *et al.*, 1974; Falchuk and Strober, 1974; Fry *et al.*, 1974; Goldstein and Heiner, 1970; Hekkens *et al.*, 1972; Kasarda, 1972, 1975; Kendall *et al.*, 1972; Lancaster *et al.*, 1975; Laplane, 1972; Morganroth *et al.*, 1972; Rossipal and Palm, 1971; Schwob *et al.*, 1972; Seah *et al.*, 1972; Self *et al.*, 1969; Shmerling and Haring, 1971; Shmerling and Shiner, 1972; Strober *et al.*, 1975; Strumeyer and Fisher, 1972, 1973).

The pathogenesis of dermatitis herpetiformis is not fully understood. An immunologic mechanism is suggested by the finding of immunoglobulin A deposits in the dermal papillae of most affected patients (Katz and Strober, 1978; Marks and Shuster, 1970; Seah *et al.*, 1973; Van der Meer, 1969). Eterman *et al.* (1977), however, examined these IgA deposits and found no antibodies to wheat. More recent studies have demonstrated the presence of wheat specific IgG antibodies in sera from dermatitis herpetiformis and gluten-sensitive enteropathy patients (Huff *et al.*, 1979; Kavai *et al.*, 1977). Massey *et al.* (1977) have suggested that gluten entering the serum from a damaged intestinal mucosa forms an immune complex which activates the complement in the skin via the alternative pathway to cause an inflammatory reaction. The presence of IgA in such immune complexes has been reported (Zone and Provost, 1979).

Since the concentration of Wheat Flour in cosmetics is low (≤1%) and the proportion of the gluten fraction of Wheat Flour is no greater than 17% (net gluten concentration ≤.17%), there is little likelihood that enough wheat gluten could be absorbed by the percutaneous route or by inadvertent ingestion from cosmetic products containing Wheat Flour to precipitate a manifestation of either cutaneous or gastrointestinal symptoms.

Wheat Starch As much as two pounds of starch can be ingested per day by compulsive starch eaters (Allan and Woodruff, 1963; Merkatz, 1961; Silverman and Perkins, 1966; Warshauer, 1966). It is generally in the form of laundry starch, and on the basis of 14% moisture content, this provides 3160 calories. These people usually become obese and prone to iron-deficiency anemia; some have an enlargement of the parotid glands, and one patient, who consumed 3 to 4 pounds of starch per day, developed a starch gastrolith (Allan and Woodruff, 1963).

Inhalation Studies Studies of respiratory allergic disorders have focused on millers, bakers, and other people exposed chronically to flour dust (Baagoe, 1933; Beritic and Valic, 1971; Beritic and Zagar, 1972; Blands *et al.*, 1976; Castberg and Sorenson, 1948; Guibert *et al.*, 1963; Hendrick *et al.*, 1976; Herxheimer, 1967a, 1967b, 1973; Heyl *et al.*, 1970; Nakazawa *et al.*, 1972; Popa *et al.*, 1970; Schmidt, 1938; Schwartz, 1947; Valic and Stahuljak, 1971; Van Dishoeck and Roux, 1940, 1941; Van Vonno and Struycken, 1933; Woitowitz *et al.*, 1971a, b; Young, 1974). The evidence available indicates that flour hypersensitivity is acquired through chronic inhalation and an inherited allergic disposition. Wheat Flour contains 40 antigens, some showing partial immunological identity (Blands *et al.*, 1976). Symptoms of the disturbance include allergic asthma, chronic bronchitis, vasomotor rhinitis,

eczema, and skin hypersensitivity. The likelihood of skin sensitization (formation of antibody) increases with time (Herxheimer, 1967a, 1967b, 1973). The average time required for development of flour sensitization in bakers with chronic exposure was 10.8 years (Schwartz, 1947).

Since the concentration of Wheat Flour in cosmetics is low (≤1%) and the cleansing preparations containing flour offer little chance of chronic inhalation, acquisition of flour sensitive allergy through this route is extremely unlikely. Face powder formulations containing Wheat Starch afford a more obvious inhalation exposure potentiality; but in consideration of the experience with bakers and the lack of evidence that starch alone can cause allergy, there is little likelihood that Wheat Starch in cosmetic products could induce asthma.

SUMMARY

Wheat Flour, a natural product obtained from wheat grain, consists primarily of starch and gluten fractions. Wheat Flour is used at low concentrations (>0.1% to 1%) in one cleansing preparation, and Wheat Starch is used at concentrations up to 25% in four face powder formulations.

Since Wheat Flour is composed almost wholly of gluten and starch, the safety assessment of the flour is based essentially on the observations made in the testing and use of the gluten and starch separately. Practically no relevant toxicologic testing has been done directly on the flour itself.

These ingredients are not toxic when administered orally. Wheat products are digested and absorbed by the normal human gastrointestinal tract. Ingestion of up to two pounds of starch per day produced only obesity and iron-deficiency anemia in human beings. Immunologic reactions to wheat have been demonstrated and may play a role in the pathogenesis of dermatitis herpetiformis and gluten sensitive enteropathy, but it is unlikely that enough gluten could be ingested accidentally from cosmetic products containing Wheat Flour to elicit such reactions.

Dermatologic studies show these ingredients to be nonirritating and nonsensitizing.

Studies of allergic respiratory disorders caused by chronic inhalation of Wheat Flour dust are numerous, but the cosmetic use of this ingredient does not provide the conditions under which such sensitization is likely to occur.

CONCLUSIONS

On the basis of the available information presented herein, the Panel concludes that Wheat Flour and Wheat Starch are safe as cosmetic ingredients in the present practices of use and concentration.

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