Final Report on the Safety Assessment of Aluminum Starch Octenylsuccinate[1]

Aluminum Starch Octenylsuccinate is the aluminum salt of the reaction product of octenylsuccinic anhydride with starch. It is used in cosmetics at concentrations as high as 30% as an anticaking agent and a nonaqueous viscosity increasing agent. No information was available on the presence of impurities in the cosmetic-grade ingredient. When used in foods, Aluminum Starch Octenylsuccinate is identified as a modified food starch, and is subject to limitations on heavy metal residues. Oral studies using Aluminum Starch Octenylsuccinate or its related sodium salt produced no adverse systemic, reproductive, or developmental effects. Dermal injections produced no abnormal skin or systemic reactions in guinea pigs. Ocular toxicity was assessed in rabbits and using an in vitro test (chorioallantoic membrane vascular assay). In both cases no toxicity was seen. An acute inhalation toxicity study in rats was negative. Clinical tests indicated little irritation potential and no sensitization. Absent data on impurities in cosmetic-grade material, it was determined that such material should meet the same impurities requirements established for modified food starches. Based on these available data the Cosmetic Ingredient Review Expert Panel concluded that Aluminum Starch Octenylsuccinate is safe as used in cosmetic formulations provided that established limitations imposed on heavy metal concentrations are not exceeded.

INTRODUCTION

This report is a compilation of data concerning the safety of Aluminum Starch Octenylsuccinate (CAS no. 9087-61-0) for use in cosmetics.

CHEMISTRY

Definition and Structure

Aluminum Starch Octenylsuccinate is the aluminum salt of the reaction product of octenylsuccinic anhydride with starch (Wenninger and McEwen 1997). A synonym is starch octenylbutanedioate, aluminum salt (National Starch and Chemical Co. 1998).

Method of Manufacture

Food-grade Aluminum Starch Octenylsuccinate is prepared by treatment of granular form starch with not more than 2% octenylsuccinic anhydride (based on starch), in the presence of alkali. When the reaction has gone to completion, the mixture is treated with aluminum sulfate, not more than 2% based on starch. The granular product is recovered by filtration, washing, and drying. It conforms to the structure shown in Figure 1 (Association des Amidonneries de Mais 1969; National Starch and Chemical Company 1998).

The substitution on the hydroxyls reduces the tendency of the starch to associate in solution, lose clarity, and form gels. The extent of substitution is low and polyelectrolyte properties result from the introduction of the succinate ester groups (Federation of American Societies for Experimental Biology [FASEB] 1979).

Chemical and Physical Properties

Cosmetic-grade Aluminum Starch Octenylsuccinate did not absorb light in the 200 to 400-nm range (National Starch and Chemical Company 1998). Unpublished data submitted by industry indicated that the average particle size for Aluminum Starch Octenylsuccinate was 13.25 μm, with 95% of particles between 4.74 and 21.81 μm in one run and an average size of 13.16 μm, with 95% between 6.05 and 21.81 μm in another run (Cosmetic, Toiletry, and Fragrance Association [CTFA] 1999a). These particle dimensions are larger than the median aerodynamic diameter of 4 ± 0.3 μm established as a respirable particulate mass (Willeke and Baron 1993).

USE

Cosmetic

Aluminum Starch Octenylsuccinate is used in cosmetic formulations as an anticaking agent and a viscosity-increasing agent—nonaqueous (Wenninger and McEwen 1997). As of January 1998, this ingredient was reported to be used in 172 formulations as shown in Table 1 (FDA 1998). Data submitted by industry (CTFA 1998b, 1999b) indicated that Aluminium Starch Octenylsuccinate was used at the concentrations listed in Table 1. Companies that reported use of Aluminum Starch Octenylsuccinate in product categories that included sprays were asked if they

Received 14 December 2001; accepted 6 March 2002.

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International Journal of Toxicology, 21(Suppl. 1):1–7, 2002

1091-5818/02 $12.00 + .00
DOI: 10.1080/10915810290096379

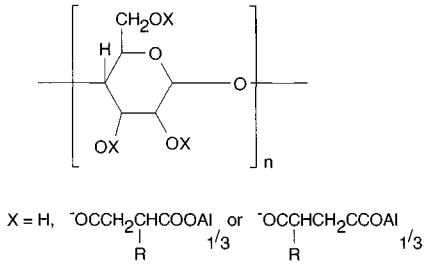

FIGURE 1

Aluminum Starch Octenylsuccinate. The R group is $CH_3(CH_2)_4CH{-}CHCH_2$. The residual 2/3 of the aluminum ion's valencies are satisfied by salt formation with sulfate ion or carboxylate ion from the starch octenyl succinate.

used this ingredient in sprays—the companies that responded indicated that they did not use Aluminum Starch Octenylsuccinate in spray products (CTFA 1999b).

One supplier of Aluminum Starch Octenylsuccinate recommended the following concentrations of use: 2% to 4% in lotions and creams (including sunscreens), 2% to 25% in powders, 2% to 10% (or, in some instances up to 30%) in color cosmetics, 2% to 10% in antiperspirants, and 2% to 25% in shaving products (National Starch and Chemical Company 1998). Another source indicated use at 10% in a barrier ointment and 8% in a lip treatment ointment (CTFA 1998a).

Aluminum Starch Octenylsuccinate is listed in the *Japanese Comprehensive Licensing Standards of Cosmetics by Category* (CLS) (Rempe and Santucci 1997). That which conforms to the specification of the *Japanese Cosmetic Ingredient Codex* has precedent for use without restriction in all CLS categories

TABLE 1

Frequency of use of Aluminum Starch Octenylsuccinate (FDA 1998)

Product category (No. formulations in category) (FDA 1998)	No. containing ingredient	Concentration of use (%) (CTFA 1998b, 1999b)
Bubble baths (200)	1	—
Other bath preparations (159)	1	—
Eyeliner	—	10
Eye shadow (506)	7	1–30
Eye lotion (18)	1	1.5–5
Mascara (167)	2	0.5
Other eye makeup preparations (120)	1	—
Powders (247)	16	—
Other fragrance preparations (148)	1	2
Hair sprays (aerosol fixatives) (261)	2	—
Blushers (all types) (238)	8	9–30
Face powders (250)	39	1–15
Foundations (287)	15	1–25
Lipstick (790)	9	15
Makeup bases (132)	2	8
Other makeup preparations (135)	6	2.5–25
Deodorants	—	4
Other personal cleanliness products (291)	7	—
Aftershave lotion (216)	5	1.5–5
Other shaving preparation products (60)	2	—
Skin cleansing (cold creams, cleansing lotions, liquids, and pads)	—	2
Face and neck skin care (excluding shaving) (263)	2	0.5–2
Body and hand skin care (excluding shaving) (796)	15	1.5–10
Moisturizing creams, lotions, powders, and sprays (769)	6	1–5
Night creams, lotions, powders, and sprays	—	1–3
Paste masks (Mud packs) (255)	3	1–6
Other skin care preparations (692)	14	5
Suntan gels, creams, and liquids (136)	2	—
Indoor tanning preparations (62)	3	5
Other suntan preparations (38)	2	—
Total for 1998	**172**	

except eyeliner preparations, for which it has no precedent for use.

Food

Aluminum Starch Octenylsuccinate is listed as a modified food starch in the *Food Chemicals Codex* (National Academy of Sciences 1996). Modified food starches are defined as "products of the treatment of any of several grain or root-based native starches (e.g., corn, sorghum, wheat, potato, tapioca, sago, etc.) with small amounts of certain chemical agents, which modify the physical characteristics of the native starches to produce desirable properties." Aluminum Starch Octenylsuccinate is identified as a starch ester. Food-grade Aluminum Starch Octenylsuccinate must comply with the residue limits listed in Table 2, and, in the initial synthesis reaction, octenylsuccinic anhydride shall not exceed 2% of starch, and, in the final synthesis reaction, aluminum sulfate shall not exceed 2% of starch.

Modified food starches are cleared for use in food (Rothschild 1990) and function as thickeners, colloidal stabilizers, and binders (National Academy of Sciences 1996).

In 1979, FASEB evaluated starch and modified starches for status as generally recognized as safe (GRAS) food ingredients. For the evaluation of Aluminum Starch Octenylsuccinate, the committee was presented with two oral dosing studies using albino rats: a 4-week nutritional study (Food and Drug Research Laboratories 1961), and an 8-week toxicity study (Food Research Laboratories 1950a). These studies are cited in the Animal Toxicology section of this report. The FASEB (1979) report acknowledged the negative findings of these studies but noted that the studies were short-term and therefore "insufficient to answer questions concerning the possible chronic toxicity of these succinates particularly in view of the lack of information on their consumption levels. The Select Committee considers it desirable to undertake long-term animal feeding studies with these modified starches." The report concluded that "while no evidence in the available information on ... starch aluminum octenylsuccinate demonstrates a hazard to the public when (it is) used at levels that are now current and in the manner now practiced, uncertainties exist requiring that additional studies should be conducted."

TABLE 2

Residue limitations for food-grade Aluminum Starch Octenylsuccinate (National Academy of Sciences, 1996)

Residue	Limit
Arsenic (as As)	Not more than 3 mg/kg
Crude fat	Not more than 0.15%
Heavy metals (as Pb)*	Not more than 0.002%
Lead*	Not more than 1 mg/kg
pH of dispersions	Between 3.0 and 9.0
Protein	Not more than 0.5%
Sulfur dioxide	Not more than 0.005%

*No further details given for the two limits on lead.

GENERAL BIOLOGY

Sun-Protection Factor Enhancement

Guth et al. (1991) reported that addition of 5% Aluminum Starch Octenylsuccinate can enhance the sun-protection factor (SPF) of a titanium dioxide formulation by "as much as 40%." A formulation containing 1% titanium dioxide had an SPF of 5.6; a formulation containing 1% titanium dioxide and 5% Aluminum Starch Octenylsuccinate had an SPF of 8.1.

Metabolism

Kelley (1991) reported detection of 2-(2′-octenyl)succinic acid and several metabolites in the urine of 17 infants and children fed formulas that used octenylsuccinate-modified cornstarch as an emulsifying agent. Increased urine concentrations of glutarate and 2-ketoglutarate were also detected and could have arisen from other components of the formulas. In some instances, the urinary organic acid pattern was "mistaken for a primary metabolic disease." Blood concentrations of octenylsuccinic acid ranged from 9.5 to 57.9 μmol/l (five children tested). A 100 kcal/kg/day quantity of formula was estimated to contain 50 to 70 mg/kg/day of octenylsuccinic acid. Octenylsuccinic acid was considered to have become at least partially liberated from the starch following ingestion and 10% to 25% was estimated to have been absorbed and ultimately excreted in the urine. The metabolism of octenylsuccinic acid was considered to be similar to that of the anticonvulsant, valproic acid.

ANIMAL TOXICOLOGY

Oral Toxicity

Short-Term

Groups of 10 male albino rats were fed 1.5 or 3.0 g of an aluminum octenylsuccinate derivative of a waxy thin-boiling starch every day for 4 weeks. A control group was fed the nonmodified starch. Weight gain, behavior, and growth were comparable among test and control rats (Food and Drug Research Laboratories 1961).

An 8-week feeding study was conducted using albino weanling rats to evaluate the safety of Aluminum Starch Octenylsuccinate for use in contact with food wrappings at an expected use concentration of 0.1%. Groups of 12 rats (6 each sex) were fed a 35% starch diet that had 1% or 10% Aluminum Starch Octenylsuccinate with complementary amounts of corn starch. Because no toxic signs were observed, the 1% dose was increased to 25% Aluminum Starch Octenylsuccinate at week 4. Control rats were fed corn starch. Other aspects of the diet were nutritionally adequate. Water was provided ad libitum. Body weight and feed consumption were measured weekly, observations were made of normality of behavior and general physical condition, and complete blood counts and blood sugar and nonprotein nitrogen concentrations were measured at the end of study. All of these parameters were similar between rats fed sodium starch

octenylsuccinate and those of the control group. Rats were not necropsied. Aluminum Starch Octenylsuccinate was considered safe for use in contact with food wrappings (Food Research Laboratories 1950a).

Buttolph and Newberne (1980) tested a related compound, sodium starch octenylsuccinate. It is prepared by treating granular starch with alkali and not more than 3% octenylsuccinic anhydride. Fischer 344 rats (56 days old) were fed nutritionally adequate diets containing 30% starch. The diets of test rats had 6%, 12%, or 30% of sodium starch octenylsuccinate (3, 6, or 15 g/kg/day) and a complementary amount of unmodified starch if necessary. Control rats were fed diets with 30% unmodified starch. Rats were mated and the females were fed their respective diets throughout gestation and lactation. Litters were adjusted to eight pups per litter. At weaning, four pups (two of each sex) were randomly selected from the second litter of each dam and these rats received the diets of their respective dams. Twenty rats (10 each sex) of the control and high-dose group each were killed at 30 days post weaning, and 100 rats (50 each sex) from each group were killed at 90 days post weaning. Blood and urine samples were obtained at necropsy. Growth parameters and hematologic values were unaffected but a dose-related increase in the weight of the liver (significant [$p < .05$] for females of the high-dose group at 30 days and for females of the mid- and high-dose group at 90 days), kidneys (significant [$p < .05$] for males of the high-dose group at 30 days, and of males and females of the mid and high-dose groups at 90 days), and cecum (significant [$p < .05$] for females of the high-dose group at 30 and 90 days) was noted. No treatment-related changes in serum chemistry values were observed. An increased incidence of renal corticomedullary mineralization (and a corresponding greater concentration of urinary magnesium and calcium compared to male rats) was observed in female rats of the dosed and control groups. The investigators considered that, "no adverse effects associated with feeding octenyl succinate starch occurred in rats under the conditions of this study."

Dermal Sensitization

Aluminum Starch Octenylsuccinate, as it appears in a "commercial preparation," was tested in a skin sensitization study using 10 albino guinea pigs and 3 albino rabbits. The preparation was a "free-flowing modified food starch refined from corn." Daily suspensions were prepared of the test sample (powder) in 2% Tween 80 in physiological saline.

The suspension was injected intracutaneously into a depilated site on the back. Injections were given three times during the first week and once weekly for an additional 7 weeks. Sites were examined 24 hours after each injection and observations continued for 2 weeks after the last injection. Rabbits were housed individually and guinea pigs were housed in groups of three or four. Feed and water were available ad libitum.

No abnormal skin reactions were observed. One guinea pig lost weight and died during the postdosing period, but no lesions were noted at necropsy. Another guinea pig lost weight during the latter part of the dosing period, but gained weight during the postdosing period (Food Research Laboratories 1950b).

Ocular Toxicity

Aluminum Starch Octenylsuccinate, as it appears in a commercial powder preparation, was instilled (0.1-ml volume, ~70 mg) into one conjunctival sac of each of six rabbits. Eyes were examined 1, 24, 48, and 72 hours after dosing. The corneas appeared normal and unchanged at each observation. A slight reddening of the conjunctivae was noted in all treated eyes 1 hour after dosing; the reddening was still present in five rabbits 24 hours later, but had cleared by the 48-hour observation. Slight conjunctival swelling was noted in four treated eyes 1 hour after dosing; the swelling cleared by 24 hours. All treated eyes were normal at the 48- and 72-hour observations. The test substance produced "very slight transient irritation to the conjunctivae" and was considered to be an "unlikely" ocular irritant in humans (Unilever Research 1984).

Two formulations containing 1.0% and 2.5% Aluminum Starch Octenylsuccinate were tested using the chorioallantoic membrane vascular assay (CAMVA). This in vitro assay relies on the similarity of the vascularized surface of a developing chick embryo to the conjunctiva. Each lotion was applied to the exposed chorioallantoic membrane (CAM) of 10 fertile hen's eggs. The eggs were then incubated for 30 minutes. The CAM was examined for damage such as hemorrhage, capillary injection, or the presence of ghost vessels. Neither lotion induced damage. The RC_{50} (the concentration which induced damage in 50% of the eggs) was >100% and the lotions were considered nonirritating (Stephens and Associates 1996; MB Research Labs 1997).

Aluminum Starch Octenylsuccinate was tested at a concentration of 100% in an eyeshadow that contained 15% of it in the product. The product was placed in the unrinsed eye(s) of six rabbits three times. On days 1, 2 and 3 after instillation, the conjunctiva(s) of one, three, and one rabbit(s), respectively, were scored a 2. The irritation potential was considered mild according to the Draize classification system. Aluminum Starch Octenylsuccinate was tested at a concentration of 100% of a blush and a foundation that had 25% of it in each product. Each product was placed in the conjunctival sac of six rabbits three times and the eyes were unrinsed. None of the rabbits that were dosed with the blush had any irritation 1 day after dosing. Irritation potential was not demonstrated as determined by the Draize classification system. One and 2 days after dosing with the foundation, four and one rabbit(s), respectively, had a score of 2. The eye irritation potential was considered minimal according to the Draize classification system (CTFA 1999c).

Inhalation

Ten rats (5/sex) were exposed to Aluminum Starch Octenylsuccinate at an atmospheric concentration of 200 mg/l for 1 hour. The animals were rinsed with tap water after the exposure to remove residual test compound. The animals were observed for pharmacologic activity and toxicity at 1, 3, 6 and

24 hours after exposure and daily thereafter for 14 days. All animals survived the observation period. No gross changes were observed at necropsy. According to the conditions of this test, Aluminum Starch Octenylsuccinate was nontoxic to rats by inhalation (Consumer Product Testing Co. 1999).

CLINICAL ASSESSMENT OF SAFETY

Dermal Irritation

Twelve women participated in a facial sting study that tested a lotion containing 3.0% Aluminum Starch Octenylsuccinate. The women were selected because prescreening had identified them as "stingers" (reacted to a 10% aqueous solution of Lactic Acid). However, none had any evidence of a dermatological disease or hypersensitivity to topical products. During testing, the lotion was applied to the labial fold of the nose. Subjective stinging was evaluated at 2.5 and 5 minutes post application. Reactions were graded 0 to 3. A cumulative score was obtained by adding grades for each woman from both evaluations. Thus, the highest possible individual score was 6 and the highest possible cumulative score was 72. The 3.0% lotion had a cumulative score of 5 that resulted from reactions in two women (one had an individual score of 4 and another had a score of 1). The lotion was considered to have "little or no potential for sting during normal intended use" (Ivy Labs 1988).

A lotion containing 1.0% Aluminum Starch Octenylsuccinate was tested in a chamber scarification test using 10 women with Fitzpatrick skin types II and III. Sites on each forearm were scratched with a needle without drawing blood. (Five other materials were tested in the same study.) The lotion was applied (0.3 ml) for three 24-hour periods. Sites were rinsed after patch removal and erythema was assessed 30 minutes later. Sites were scored on a scale of 0 to 4. The mean score on day 3 (used to determine irritancy potential) was 1.4. The lotion was considered to have "slight" irritation potential (Skin Study Center 1995).

The irritation potential of two formulations containing 2.23% and 2.5% Aluminum Starch Octenylsuccinate were tested using 9 or 10 "sensitive skin" panelists. Occlusive patches were applied for two consecutive 24-hour periods. Neither lotion induced erythema. The 2.23% lotion produced a nonsignificant increase in transepidermal water loss (TEWL). The TEWL was not measured for the 2.5% lotion because of equipment failure (CTFA 1996, 1997).

Dermal Sensitization

Five hand and body lotions were tested in separate human repeat-insult patch tests (RIPTs). Biosearch, Inc. (1994) studied lotion A (pH not reported) containing 1.0% (*w/w*) Aluminum Starch Octenylsuccinate in male and female (between 18 and 65 years of age) panelists. Of 102 panelists, 104 completed the study. Stephens and Associates, Inc. (1998) studied lotion B (pH 4.0) containing 1.0% (*w/w*) Aluminum Starch Octenylsuccinate; 104 of 135 male and female panelists completed the study. Clinical Research Services (1996) studied lotion C (pH 5.5) containing 2.23% (*w/w*) Aluminum Starch Octenylsuccinate; 103 of 105 males and females (between 18 and 70 years of age) completed the study. Essex Testing Clinic, Inc. (1988) studied lotion D (pH not reported), contained 3.0% (*w/w*) Aluminum Starch Octenylsuccinate; 52 of 54 (9 males and 45 females, between 23 and 63 years of age) panelists completed the study. Clinical Research Services (1997) studied lotion E (pH 5.3) containing 2.5% (*w/w*) Aluminum Starch Octenylsuccinate; 102 of 104 male and female panelists (between 18 and 65 years of age) completed the study. Panelists were dropped from each study for reasons such as noncompliance with the test protocol, excessive sensitivity to the adhesive tape used, medical conditions (unrelated to test material), participation in another study within the past 2 weeks, or a preexisting allergy. One panelist tested with lotion B was removed from study because she had a reaction to one of the other formulations that was being tested in the same study.

During the 3-week induction period, each lotion was applied under occlusive patch three times per week, for a total of nine induction exposures. Patches containing lotions A (0.2 ml) and D (0.2 g) were applied for 24 hours; patches containing lotions B, C, and E (100 or 200 μl) were applied for 48 hours. All patches were applied to the back except lotion A, which was applied to the arm. Following a 10- to 21-day nontreatment period, panelists were challenged at two sites—the original and a previously unexposed site (in most studies the second site was on the arm). Sites were scored at the time of patch removal, and after an additional 24 and 48 hours.

No reactions were noted during induction or challenge to lotions A, C, D, and E. One subject developed "mild erythema" (scored 1, the lowest nonzero score) to lotion B after the third induction exposure. It was an isolated incidence. One subject also had a score 1 reaction to lotion B at the 48-hour challenge reading of the original exposure site; the erythema resolved by the 96-hour scoring. None of the lotions were sensitizers (Biosearch, Inc. 1994 [lotion A]; Stephens and Associates, Inc. 1998 [lotion B]; Clinical Research Services, Inc. 1996, 1997 [lotions C and E]; Essex Testing Clinic, Inc. 1988 [lotion D]).

Aluminum Starch Octenylsuccinate (30.5% in a "Dark Brown Paste") was tested in an RIPT using 240 subjects. During the first 3 weeks patches of 0.02 g test material were applied three times weekly for 48 to 72 hours to the upper arm and back of the panelists. Two weeks later, a challenge patch was applied to another site. The challenge patches were removed 72 hours following application of the test material to the site and the reaction was scored 96 hours after application. The test material produced erythema (1) in two subjects and the reaction was not considered a clinically significant irritant or allergic contact dermatitis in human subjects (CTFA 1998c).

Aluminum Starch Octenylsuccinate was tested in an RIPT at a concentration of 20% using 121 men and women. Ten samples (0.3 ml) were applied to the upper arm of each subject for 24 hours for about 3 weeks using occlusive patches. Reactions

were scored 48 or 72 hours after the application of each sample under a 100-watt incandescent blue bulb. A 2-week nontreatment period followed the induction phase. The challenge patch was applied to an untreated site for 24 hours and scored 48 or 96 hours later. No subjects demonstrated contact sensitization to samples 2 to 10. Sample 1 was not applied at challenge at the sponsor's request (Hill Top Research, Inc. 1981).

An RIPT was conducted using 109 men and women and a 25% concentration of Aluminum Starch Octenylsuccinate in a commercial preparation. The occlusive patch with 0.1 ml of the test material was applied to the upper back of the subject three times weekly for 3 weeks. The subjects removed the patch at home 24 hours after application. The patches were applied to the same site unless a severe reaction developed. Following a 3-week nontreatment period, a single patch of the test material was applied to an untreated site. The patch was removed 24 hours after application and the reaction was scored 24 and 48 hours after removal. No erythematous reactions occurred during the induction or challenge phases of the study. Aluminum Starch Octenylsuccinate did not have any potential for inducing allergic sensitization (CTFA 1999d).

Aluminum Starch Octenylsuccinate (25%) was tested as a commercial preparation using 89 men and women using the same protocol as described above. One subject had a reaction scored as barely perceptible erythema. Aluminum Starch Octenylsuccinate in this preparation did not have any potential for inducing allergic sensitization (CTFA 1999d).

Aluminum Starch Octenylsuccinate (6%) was tested as a commercial preparation using 106 men and women and the same protocol as described above. One subject had a reaction scored as mild erythema. Aluminum Starch Octenylsuccinate in this preparation did not have any potential for inducing allergic sensitization (CTFA 1999d).

A 4-day minicumulative irritancy test of a commercial preparation containing 25% Aluminum Starch Octenylsuccinate had a primary irritation index (PII) of 0.0 (CTFA 1999e).

SUMMARY

Aluminum Starch Octenylsuccinate is the aluminum salt of the reaction product of octenylsuccinic anhydride with starch. It is used in cosmetic formulations as an anticaking agent and a viscosity increasing agent—nonaqueous. In January 1998 it was used in 172 cosmetic formulations. Current concentration of use data indicated use at up to 30%. When used in foods, Aluminum Starch Octenylsuccinate is identified as a "modified food starch."

Aluminum Starch Octenylsuccinate is reported to enhance the sun-protection factor of sunscreen formulations. Cosmetic-grade Aluminum Starch Octenylsuccinate did not absorb light in the 200 to 400-nm range.

Oral doses of Aluminum Starch Octenylsuccinate at concentrations up to 25% and oral doses of a related compound up to 30% produced no adverse effects in animal studies. Aluminum Starch Octenylsuccinate was not an ocular irritant. A commercial preparation of Aluminum Starch Octenylsuccinate produced no abnormal skin reactions in guinea pigs and rabbits. Aluminum Starch Octenylsuccinate was nontoxic to rats by inhalation.

Clinical facial sting, chamber scarification, and closed patch studies indicated little irritation potential with Aluminum Starch Octenylsuccinate (tested up to 3% in formulation). Aluminum Starch Octenylsuccinate, tested at up to 25% in formulation, was not a sensitizer in clinical RIPTs.

DISCUSSION

In the absence of data indicating concentrations of toxic metals that can be found as contaminants in this ingredient, the Cosmetic Ingredient Review (CIR) Expert Panel limited concentrations of the toxic metals in cosmetic-grade Aluminum Starch Octenylsuccinate to the same concentrations as have been established for food-grade modified starches. Thus, cosmetic-grade Aluminum Starch Octenylsuccinate must not contain more than 3 mg/kg of arsenic (as As), not more than 0.002% heavy metals (as Pb), and not more than 1 mg/kg of lead. These limits match the specifications listed in the *Food Chemicals Codex* for modified food starches.

The Expert Panel acknowledged the study that reported an enhancement of the sun-protection factor of a sunscreen formulation with the addition of Aluminum Starch Octenylsuccinate. Cosmetic-grade Aluminum Starch Octenylsuccinate did not absorb light in the 200 to 400-nm range.

Frequency of use data indicated that Aluminum Starch Octenylsuccinate is used in formulations where inhalation is a route of exposure. Data on particle size distribution of Aluminum Starch Octenylsuccinate demonstrated that this material is not respirable.

The Expert Panel considered the absence of any skin irritation or sensitization at test concentrations as great as 30.5% to support the safety of even the largest concentration reported to be used in cosmetic formulations.

CONCLUSION

Based on the available data, the CIR Expert panel concludes that Aluminum Starch Octenylsuccinate is safe as used in cosmetic formulations provided that established limitations imposed on heavy metal concentrations are not exceeded.

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