Amended Safety Assessment of Aluminum Starch Octenylsuccinate
As Used in Cosmetics

Status: Re-Review for Panel Review
Release Date: May 11, 2018
Panel Meeting Date: June 4-5 2018
Memorandum

To: CIR Expert Panel Members and Liaisons
From: Alice Akinsulie
Scientific Analyst/Writer
Date: May 11, 2018
Subject: Amended Safety Assessment of Aluminum Starch Octenylsuccinate as Used in Cosmetics

Enclosed is the Re-Review of Aluminum Starch Octenylsuccinate as Used in Cosmetics (starch062018rep). In 2002, the Panel published a safety assessment with the conclusion that Aluminum Starch Octenylsuccinate is safe as used in cosmetic formulations provided that established limitations imposed on heavy metal concentrations are not exceeded; the limitations were identified in the Discussion of the report. The Expert Panel also acknowledged a study reported an enhancement of the sun protection factor of a sunscreen formulation with the addition of Aluminum Starch Octenylsuccinate.

Because it has been 15 years since the safety assessment on the above ingredients was published, the Panel is being asked to determine whether the conclusion should be reaffirmed, or, if a re-review is necessary. Additionally, the following 7 ingredients are being proposed for inclusion in this assessment:

- Acacia Seyal Gum Octenylsuccinate
- Calcium Starch Octenylsuccinate
- Hydrolyzed Hydroxypropylsuccinate
- Quinoa Starch Octenylsuccinate
- Sodium Glycogen Octenylsuccinate
- Sodium Hydroxypropyl Cyclodextrin Octenylsuccinate
- Sodium Trehalose Octenylsuccinate

According to 2018 FDA VCRP data, Aluminum Starch Octenylsuccinate is reported to be used in 786 formulations, 744 of which are in leave-on formulations; 699 uses are reported in formulations that result in dermal contact. None of the proposed add-ons are reported to the FDA VCRP as in use.

The frequency of use of Aluminum Starch Octenylsuccinate has increased since the original safety assessment was prepared. In 1998, Aluminum Starch Octenylsuccinate was reported to be used in 172 formulations, the majority of which resulted in dermal contact. A concentration of use survey is currently being conducted by the Council, and once those data are received they will be incorporated into the report. However, according to the original report, Aluminum Starch Octenylsuccinate was used in leave-on products at concentrations of 0.5-30%.

The original report is included with this submission for your review (starch062018prev). To facilitate your review, relevant information from the original report are included throughout the text of the re-review document (indicated by italics), and the original Discussion is also included. It should be noted that no new data were found in the published literature.

The Panel is now being asked to consider whether a re-review is appropriate, first considering whether the original conclusion is still valid. If the new data presented in the report simply reaffirms the original conclusion, then is it appropriate to re-open the review to include the proposed “add-ons”?

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RE-REVIEW FLOW CHART

INGREDIENT/FAMILY: Aluminum Starch Octenylsuccinate

MEETING: June 2018

PUBLIC COMMENT

CIR

EXPERT PANEL

RE-REVIEW

RPT STATUS

PUBLIC COMMENT

announce

15 years since last review

New Data; or request

IJT 21 (Suppl 1): 1-7; 2002

Re-review to Panel June 2018

PRIORITIZE LIST

Are new data cause to reopen?

YES

DRAFT AMENDED REPORT

IDA Notice

IDAM TENTATIVE AMENDED REPORT

IDAM FINAL AMENDED REPORT

Diffent Conclusion

Are new ingredients appropriate for inclusion/re-open?

YES

DRAFT AMENDED REPORT

IDA

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New Ingredient Appropriate

No

NEW DATA; or request

IJT 21 (Suppl 1): 1-7; 2002

Re-review to Panel June 2018

60 day Public comment period

DRAFT TENTATIVE AMENDED REPORT

TENTATIVE AMENDED REPORT

Issue TAR

FAR

PUBLISH

Annotations:

- If Draft Amended Report (DAR) is available, the Panel may choose to review; if not, CIR staff prepares DAR for Panel Review.

- 7 proposed additions
**CIR History of: Aluminum Starch Octenylsuccinate**

A Rereview on Aluminum Starch Octenylsuccinate was issued on March, 2018.

**67th CIR Expert Panel Meeting (May 18-19, 1998)**
The Panel issued an Insufficient Data Announcement (IDA) with the following data requests on Aluminum Starch Octenylsuccinate:

1. Concentration of use
2. Methods of manufacture and chemical characterization, including impurities
3. Dermal absorption; if significantly absorbed, then gross pathology and histopathology in skin and other major organ systems associated with repeated exposures, and dermal reproductive and developmental toxicity data may be needed
4. Dermal irritation and sensitization
5. Two genotoxicity assays, one in a mammalian system; if positive, then a 2-year dermal carcinogenesis study using NTP methods may be needed
6. Inhalation studies at use particle size

**69th CIR Expert Panel Meeting (December 2-3, 1998)**
The Panel issued a Tentative Report with the following conclusion: Based on the available data, the CIR Expert Panel concludes that Aluminum Starch Octenylsuccinate is safe as used in cosmetic formulations. The available data are insufficient to support the safety of this ingredient in cosmetic products in which a primary route of exposure is inhalation.

**71st CIR Expert Panel Meeting (June, 1999) – Dr. Belsito’s Team**

According to the information received, the average particle size of Aluminum Starch Octenylsuccinate is ≈13.5 µ, and a particle of this size would not be respirable. The Panel voted unanimously in favor of issuing a Final Report with the following conclusion: Based on the available data, the CIR Expert Panel concludes that Aluminum Starch Octenylsuccinate is safe as used in cosmetic formulations.

**Rereview: June 4-5, 2018**
### Amended Safety Assessment of Aluminum Starch Octenylsuccinate – June 4th-5th, 2018 meeting – Alice Akinsulie

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**Search Strategy**

[document search strategy used for SciFinder, PubMed, and Toxnet]

[identify total # of hits / # hits that were useful]

**SearchTerms**

- Starch Octenylsuccinate
Search Engines
- Toxnet (https://toxnet.nlm.nih.gov) (includes Toxline; HSDB; ChemIDPlus; DART; IRIS; CCRIS; CPDB; GENE-TOX)
- Scifinder (https://scifinder.cas.org/scifinder)

appropriate qualifiers are used as necessary
search results are reviewed to identify relevant documents

Pertinent Websites
- wINCI - http://webdictionary.personalcarecouncil.org
- FDA databases http://www.ecfr.gov/cgi-bin/ECFR?page=browse
- FDA search databases: http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234631.htm;
- GRAS listing: http://www.fda.gov/food/ingredientspackaginglabeling/gras/default.htm
- SCOGS database: http://www.fda.gov/food/ingredientspackaginglabeling/gras/scogs/ucm2006852.htm
- Indirect Food Additives: http://www.accessdata.fda.gov/scripts/fdcc/?set=IndirectAdditives
- Drug Approvals and Database: http://www.fda.gov/Drugs/InformationOnDrugs/default.htm
- (inactive ingredients approved for drugs: http://www.accessdata.fda.gov/scripts/cder/iig/)
- HPVIS (EPA High-Production Volume Info Systems) - https://ofmext.epa.gov/hpvis/HPVISlogon
- NIOSH (National Institute for Occupational Safety and Health) - http://www.cdc.gov/niosh/
- NTIS (National Technical Information Service) - http://www.ntis.gov/
- NTP (National Toxicology Program) - http://ntp.niehs.nih.gov/
- Office of Dietary Supplements https://ods.od.nih.gov/
- FEMA (Flavor & Extract Manufacturers Association) - http://www.femaflavor.org/search/apachesolr_search/
- EU CosIng database: http://ec.europa.eu/growth/tools-databases/cosing/
- ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals) - http://www.ecetoc.org
- International Programme on Chemical Safety [http://www.inchem.org/]
- [www.google.com] - a general Google search should be performed for additional background information, to identify references that are available, and for other general information.

**Botanical Websites, if applicable**
- Dr. Duke’s - [https://phytochem.nal.usda.gov/phytochem/search]
- GRIN (U.S. National Plant Germplasm System) - [https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx]
- National Agricultural Library NAL Catalog (AGRICOLA) - [https://agricola.nal.usda.gov/]
- The Seasoning and Spice Association List of Culinary Herbs and Spices - [http://www.seasoningandspice.org.uk/ssa/background_culinary-herbs-spices.aspx]

**Fragrance Websites, if applicable**
- IFRA (International Fragrance Association) – [http://www.ifraorg.org/]
- Research Institute for Fragrance Materials (RIFM)
67th CIR Expert Panel Meeting (May 18-19, 1998) – Dr. Schroeter’s Team

Aluminum Starch Octenylsuccinate

Dr. Schroeter stated that his Team determined that the following data are needed for completion of the Panel’s safety assessment on Aluminum Starch Octenylsuccinate:

1. Concentration of use
2. Methods of manufacture and chemical characterization, including impurities
3. Dermal absorption; if significantly absorbed, then gross pathology and histopathology in skin and other major organ systems associated with repeated exposures, and dermal reproductive and developmental toxicity data may be needed
4. Dermal irritation and sensitization
5. Two genotoxicity assays, one in a mammalian system; if positive, then a 2-year dermal carcinogenesis study using NTP methods may be needed
6. Inhalation studies at use particle size

1Gross pathology and histopathology in skin and other major organ systems associated with repeated exposures are data that would be expected from what is commonly referred to as a 28-day dermal toxicity study. The CIR Expert Panel is concerned that specifying a type of study may inhibit those who want to gather data using other study designs. For example, the Expert Panel would consider a dermal reproductive and developmental toxicity study in which gross pathology and histopathology data are gathered on the F0 generation to be sufficient if done at or above current concentrations of use of the ingredient.

Dr. Belsito noted that Aluminum Starch Octenylsuccinate is a GRAS ingredient, and that his Team determined that if the cosmetic grade material meets the specifications established for the food grade material, then items 2, 3, and 5 above could be eliminated.

Dr. Schroeter agreed that Aluminum Starch Octenylsuccinate has been approved for use as a food additive, but noted that such approval was based on ingestion studies and not dermal application studies.

The Panel voted unanimously in favor of issuing an Insufficient Data Announcement on Aluminum Starch Octenylsuccinate with the following data requests:

1. Current concentration of use
2. Dermal irritation and sensitization
3. Inhalation studies at use particle size

1This presumes that this ingredient would meet the food grade description of purity, limitation on contaminants, etc.

Dr. Bergfeld noted that the minutes should reflect that if the descriptions of food and cosmetic grade Aluminum Starch Octenylsuccinate are not identical, then the six data requests mentioned by Dr. Schroeter will be needed.

69th CIR Expert Panel Meeting (December 2-3, 1998) – Dr. Schroeter’s Team

Aluminum Starch Octenylsuccinate

Dr. Schroeter stated that the following data were received in response to the insufficient data announcement that was issued at the May 18-19, 1998 Panel meeting: (1) typical concentration of use, (2) method of manufacture, (3) UV absorption, and (4) skin irritation and sensitization. He noted that the only studies requested by the Panel that have not been received are inhalation studies (at use particle size). Thus, Dr. Schroeter’s Team concluded that Aluminum Starch Octenylsuccinate is safe as used, except for formulations that are aerosol products.
Dr. Belsito noted that the use concentrations of Aluminum Starch Octenylsuccinate are reported to be as high as 30% in some powders and 25% in some shaving products, but that the data available for evaluating skin irritation and sensitization potential were at test concentrations up to 3%. With this in mind, he said that his Team had reservations about approving a safe as used concentration that is eight times higher than the test concentration in the skin irritation and sensitization study, taking into consideration that Aluminum Starch Octenylsuccinate is used in 172 cosmetic products. Thus, Dr. Belsito=s Team concluded that Aluminum Starch Octenylsuccinate is safe at concentrations up to 3% in leave-on products, safe as used in rinse-off products, and that the data are insufficient for evaluating the safety of this ingredient in aerosolized products.

Dr. McEwen recalled that Aluminum Starch Octenylsuccinate powder (suspension in 2% Tween 80) was tested in a guinea pig maximization test.

Dr. Belsito said that the report text indicates that Aluminum Starch Octenylsuccinate, as it appears in a commercial preparation, was tested, and that there is no indication of the ingredient concentration that is used in the commercial preparation. Dr. Belsito said that he would be willing to accept the study if the ingredient concentration in the commercial preparation is identified.

Dr. Bergfeld said that the report conclusion that will be issued could be modified, without further review by the Panel, if the concentration in the commercial preparation is near 100% or higher than 3%.

The Panel unanimously approved the issuance of a Tentative Report.

Ms. Fise noted that the cosmetic use section of the report text contains information on use concentrations that is based on the recommendations of a supplier of Aluminum Starch Octenylsuccinate. She recommended that this information be deleted from the text, and asserted that the use concentration data in this section should reflect actual ingredient use concentrations that have been reported. Ms. Fise wanted to avoid a potential worse case scenario in which a safe as used conclusion would be based on use concentrations recommended by a supplier, rather than actual reported use concentrations.

Dr. Andersen noted that the Panel should recognize that the recommended use concentrations from the supplier are not necessarily indicative of any concentration in a real product.

Dr. Belsito also indicated his preference for actual use concentrations, but did not favor deleting the supplier=s recommendation, taking into consideration that concentration of use data are no longer being provided to FDA.

Dr. Bailey said that Ms. Fise had raised a good point. He agreed that the term Asafe as used@ needs to qualified such that the reader knows exactly which concentrations are being referred to as well as their origin.

Dr. Bergfeld asked Dr. Bailey to update the Panel as to what is happening at FDA. She wanted to know if any programs that would provide the Panel with concentration of use data would be reinstated.

Dr. Bailey said that FDA=s intent at this point is to resume operation of the voluntary reporting program early in 1999.

Dr. Bergfeld thought that it would be appropriate for the Panel to send a letter to FDA, thanking the agency for this proposal.

Dr. Andersen said that such a letter would be appropriate, particularly if concentration of use data will be reported in the voluntary program.

Dr. Bailey said that if the Panel is interested in having the voluntary reporting system upgraded to include concentration of use data, this level of interest can be communicated to FDA in detail.
Dr. Belsito noted that, at the December 2-3, 1998 Panel meeting, the Panel issued a Tentative Report with the following conclusion: Based on the available data, the CIR Expert Panel concludes that Aluminum Starch Octenylsuccinate is safe as used in cosmetic formulations. The available data are insufficient to support the safety of this ingredient in cosmetic products in which a primary route of exposure is inhalation. Dr. Belsito also noted that information on particle size was received since this conclusion was issued. According to the information received, the average particle size of Aluminum Starch Octenylsuccinate is $\approx 13.5 \mu m$, and a particle of this size would not be respirable. Thus, Dr. Belsito’s Team concluded that the statement relating to inhalation exposure should be deleted from the report conclusion.

The Panel voted unanimously in favor of issuing a Final Report with the following conclusion: Based on the available data, the CIR Expert Panel concludes that Aluminum Starch Octenylsuccinate is safe as used in cosmetic formulations.

Dr. Belsito recommended deletion of the last paragraph of the report discussion, which reads as follows: “The Expert Panel initially considered that the maximum concentration of 3.0% used in clinical sensitization tests might be appropriate as a basis for limiting the safe concentrations of this ingredient. However, the availability of animal tests using a suspension of pure ingredients injected intracutaneously were negative. This suggests that concentrations much greater than 3.0% would not produce sensitization in clinical tests.” Dr. Belsito’s recommendation was based on the fact that data at higher concentrations were received since the Tentative Report was issued.

In response to Dr. Bergfeld’s question, Dr. Belsito confirmed that the issue of particle size will be addressed in the report discussion.

Dr. Shank recommended deletion of the paragraph in the report discussion that addresses the Panel’s need for inhalation toxicity data. The Panel agreed with Dr. Shank’s recommendation.

Dr. Andersen said that because the Tentative conclusion that was issued is being revised, the Panel needs to decide whether to issue the CIR report on Aluminum Starch Octenylsuccinate as a revised Tentative Report or a Final Report.

Ms. Fise recommended that the Panel issue a revised Tentative Report, so that any interested parties may have an opportunity to comment on the Panel’s revised conclusion on the safety of Aluminum Starch Octenylsuccinate.

The Panel voted unanimously in favor of issuing a revised Tentative Report with the following conclusion: Based on the available data, the CIR Expert Panel concludes that Aluminum Starch Octenylsuccinate is safe as used in cosmetic formulations.
Amended Safety Assessment of Aluminum Starch Octenylsuccinate
As Used in Cosmetics

Status: Re-Review for Panel Review
Release Date: May 11, 2018
Panel Meeting Date: June 4-5 2018
INTRODUCTION

The safety of Aluminum Starch Octenylsuccinate previously has been reviewed by the Cosmetic Ingredient Review (CIR) Expert Panel (Panel). A final report with a conclusion stating that Aluminum Starch Octenylsuccinate is safe as used in cosmetic formulations provided that established limitations imposed on heavy metal concentrations are not exceeded, was published in 2002.1 Those limitations are outlined in the Discussion of the original report, and state that the Panel limited concentrations of toxic metals in “cosmetic-grade” Aluminum Starch Octenylsuccinate to the same concentrations as have been established for food-grade modified starches. In accordance with its Procedures, the CIR evaluates the conclusions of previously-issued reports every 15 years; therefore this re-review document has been prepared.

According to the web-based International Cosmetic Ingredient Dictionary and Handbook (wINCI; Dictionary), Aluminum Starch Octenylsuccinate functions mostly as an absorbent, anticaking agent, and non-aqueous viscosity increasing agent.2 (Table 1) These reported functions are mostly the same as those indicated in the 2002 assessment, although absorbent is a new function for Aluminum Starch Octenylsuccinate.

Additionally, the following 7 ingredients are being proposed for inclusion in this assessment:
Acacia Seyal Gum Octenylsuccinate
Calcium Starch Octenylsuccinate
Hydrolyzed Hydroxypropyl Starch Octenylsuccinate
Quinoa Starch Octenylsuccinate
Sodium Glycogen Octenylsuccinate
Sodium Hydroxypropyl Cyclodextrin Octenylsuccinate
Sodium Trehalose Octenylsuccinate

Most of these ingredients are products obtained by the reaction of octenylsuccinic anhydride and have the viscosity increasing agent/humectant function in cosmetics in common. A complete listing of the functions of all of the octenylsuccinates included in this report, are presented in Table 1.

CIR has previously issued a Final Report on Polysaccharide Gums, which included several similar ingredients, i.e., Hydrolyzed Corn Starch Octenylsuccinate, Sodium Dextrin Octenylsuccinate, Sodium Starch Octenylsuccinate, and TEA- Dextrin Octenylsuccinate.3 The Panel concluded that these ingredients are safe in the present practices of use and concentration in cosmetics.

CIR safety assessments include relevant published and unpublished data that are available for each endpoint that is evaluated. Published data are identified by conducting an exhaustive search of the world’s literature. A listing of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints that CIR typically evaluates, is provided on the CIR website (http://www.cir-safety.org/supplementaldoc/preliminary-search-engines-and-websites; http://www.cir-safety.org/supplementaldoc/cir-report-format-outline). Unpublished data are provided by the cosmetics industry, as well as by other interested parties.

It should be noted that no new data were found in the published literature; however summaries of safety test data and the Discussion from the published 2002 report are italicized in this document. The complete report is available on the CIR website. (http://www.cir-safety.org/ingredients)

CHEMISTRY

Definition and Structure

Aluminum Starch Octenylsuccinate is an aluminum salt that is derived from the reaction product of octenylsuccinate anhydride with starch2. (Figure 1.) The definitions of Aluminum Starch Octenylsuccinate and the proposed add-ons are presented in Table 1. All of these ingredients are esters of a polysaccharide and 2-octenylsuccinic acid (Figure 1) (typically formed from the anhydride).

![Figure 1. 2-octenylsuccinic acid](image-url)
Physical and Chemical Properties

Physical and chemical properties of Aluminum Starch Octenylsuccinate are described in Table 2.

Unpublished data submitted by industry indicated that the average particle size for Aluminum Starch Octenylsuccinate was 13.25μm, 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.¹ Cosmetic-grade Aluminum Starch Octenylsuccinate did not absorb light in the 200- to 400-nm range.

Method of Manufacture

Food-grade Aluminum Starch Octenylsuccinate is made by the treatment of granular form of starch with 2% starch based octenylsuccinic anhydride in alkali.¹ The mixture is then treated with aluminum sulfate, not more than 2% based on starch.

Aluminum Starch Octenylsuccinate is an aluminum salt that is obtained as corn starch reacts with 2-octenylsuccinic anhydride.⁴ It is produced by utilizing corn starch and deionizing water to prepare a 35% (w/w) suspension. The suspension was washed out with deionized water and then filtered and placed in an oven at 40 degree centigrade. Sodium hydroxide and different of aluminum sulfate solution was gradually added to the suspension. The suspension is then washed with deionized water then filtered and placed in an oven to obtain it in powdered form.

Impurities

Impurities data were not found in the published literature, and unpublished data were not submitted. [Data from the original safety assessment are summarized below.]

Food-grade Aluminum Starch Octenylsuccinate must comply with specified residue limits.¹ At the time of the original safety assessment, those limits were not more than (NMT) 3 mg/kg arsenic (as As), NMT 0.15% crude fat, NMT 0.002% heavy metals (as Pb), NMT 1 mg/kg lead, and NMT 0.5% protein, and NMY 0.005% sulfur dioxide; additionally, the pH of the dispersions were to be between 3.0 and 9.0. 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.

USE

Cosmetic

The safety of the cosmetic ingredients included in this assessment is evaluated based on data received from the U.S. Food and Drug Administration (FDA) and the cosmetics industry on the expected use of these ingredients in cosmetics. Use frequencies of individual ingredients in cosmetics are collected from manufacturers and reported by cosmetic product the cosmetic industry in response to a survey, conducted by the Personal Care Products Council (Council), of maximum reported use concentrations by product category.

According to 2018 VCRP data, Aluminum Starch Octenylsuccinate is reported to be used in 786 formulations; 744 of those uses are leave-on formulations, and 699 result in dermal contact.⁵ The frequency of use has increased since the original report was issued; in 1998, VCRP data indicated that Aluminum Starch Octenylsuccinate was used in 172 formulations, 158 of which were leave-on formulations.¹ None of the proposed add-on ingredients are listed in the VCRP as in use.

A concentration of use survey is currently being conducted by the Council; these data will be included once they are received. In the original report, concentration of use data (1998/1999) indicated that Aluminum Starch Octenylsuccinate was used at up to 30% in leave-on products.¹ Both historical and current use data are provided in Table 3.

Aluminum Starch Octenylsuccinate is reported to be used in 138 formulations applied to the eye area, in 32 formulations that can result in incidental ingestion, and in 34 formulations that come into contact with mucous membranes.⁶ Additionally, it is reported to be used in 1 baby product formulation.

Aluminum Starch Octenylsuccinate is used in cosmetic sprays and could possibly be inhaled. In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters >10 μm, with propellant sprays yielding a greater fraction of droplets/particles <10 μm compared with pump sprays.⁷,⁸ Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and thoracic regions of the respiratory tract and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount.⁹,¹⁰ Also, Aluminum Starch Octenylsuccinate is reportedly used in powders, which could also result in possible inhalation. Conservative estimates of inhalation exposures to respirable particles during the use of loose powder cosmetic products are
400-fold to 1000-fold less than protective regulatory and guidance limits for inert airborne respirable particles in the workplace.11-13

The ingredients reviewed in this safety assessment do not appear on the list of substances that are prohibited in cosmetic products that are marketed within the European Union and are not subject to any restrictions relating to their use in these products.14

Non-Cosmetic

*Aluminum Starch Octenylsuccinate* is listed as a modified food starch in the *Food Chemicals Codex.*1

Food starch-modified is a direct food additive used as a multipurpose additive. [21CFR172.892]

**TOXICOKINETIC STUDIES**

**Absorption, Distribution, Metabolism, and Excretion (ADME)**

**Oral**

2-((2’-Octenyl) succinic acid and increased levels of glutarate and 2-ketoglutarate were detected in the urine of 17 infants and children that were fed formulas that used octenyl succinate modified cornstarch as an emulsifying agent.1 In five children tested, blood concentrations of octenyl succinic acid ranged from 9.5-57.9 μmol/L. A 100 kcal/kg/day quantity of formula was estimated to contain 50-70 mg/kg/day of octenyl succinic acid. Octenyl succinic acid was considered to have become at least partially liberated from the starch following ingestion and 10-25% was estimated to have been absorbed and ultimately excreted in the urine.

**TOXICOLOGICAL STUDIES**

No additional toxicity studies were found in the published literature, and unpublished data were not submitted. Data from the original safety assessment are summarized below. Only short-term toxicity studies were available.

**Short-Term Toxicity Studies**

**Oral**

Groups of ten 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 four weeks.1 A control group was fed the non-modified starch. Weight gain, behavior and growth were comparable among test and control rats.

Groups of 12 albino weanling rats (5 female and 5 males) were fed a 35% starch diet which had 1 or 10% Aluminum Starch Octenylsuccinate with complementary amounts of corn starch. The eight-week feeding study was conducted to evaluate the safety of Aluminum Starch Octenylsuccinate for use in contact with food wrappings at an expected use concentration of 0.1%. At week 4, the 1% dose was increased to 25% Aluminum Starch Octenylsuccinate due to lack of toxic signs. *Aluminum Starch Octenylsuccinate* was considered safe for use in contact with food wrappings.

**DEVELOPMENTAL AND REPRODUCTIVE TOXICITY STUDIES**

No additional developmental and reproductive toxicity (DART) studies were found in the published literature, and unpublished data were not submitted. [Data from the original safety assessment are summarized below.]

In a DART study, a sodium starch octenyl succinate (provided as read-across for *Aluminum Starch Octenylsuccinate*) was tested.1 Fischer 344 rats (56 days old) were fed nutritionally diets containing 30% starch (6, 12, or 30% of sodium starch octenyl succinate) ranging 3, 6, or 15 g/kg per day. Control rats were fed diets with 30% unmodified starch. 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. An increased concentration of urinary magnesium and calcium compared to male rats was observed in female rats of the dosed and control groups. Oral studies using *Aluminum Starch Octenylsuccinate* or its related sodium salt produced no adverse systemic, reproductive, or developmental effects.

**DERMAL IRRITATION AND SENSITIZATION**

No additional dermal irritation and sensitization studies were found in the published literature, and unpublished data were not submitted. [Data from the original safety assessment are summarized below.]
Irritation

**Human**

The skin irritation potential of a lotion containing 3.0% Aluminum Starch Octenylsuccinate was evaluated using 12 women that reacted to a 10% aqueous solution of Lactic Acid in a facial sting study. The lotion was applied to the labial fold of the nose. Subjective stinging was evaluated at 2.5 and 5 minutes post-application. 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.

A lotion containing 1.0% Aluminum Starch Octenylsuccinate was tested in a chamber scarification test using ten 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 h periods. Sites were rinsed after patch removal and erythema was assessed 30 min later. The lotion was considered to have slight irritation potential.

Irritation potentials of the two formulations containing Aluminum Starch Octenylsuccinate at 2.23% and 2.5% were examined using 9 or 10 subjects with "sensitive skin." Occlusive patches were applied for two consecutive 24-hour periods. None of the lotions resulted in erythema. However, the crème containing Aluminum Starch Octenylsuccinate at 2.23% showed some insignificant increase in trans epidermal water loss.

**Sensitization**

**Animal**

The sensitization potential of Aluminum Starch Octenylsuccinate was investigated in a skin sensitization study using ten albino guinea pigs and three albino rabbits. No abnormal skin reactions were observed. One guinea pig lost weight and died during the post-dosing 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 post-dosing period.

**Human**

In human sensitization studies, five hand and body lotions were tested under occlusive patch three times per week for a total of nine induction exposures in separate human repeated insult patch tests (HRIPTs). Lotion A contained 1.0% Aluminum Starch Octenylsuccinate, Lotion B contained 1.0% of the product (pH of 4.0), Lotion C contained 2.23% Aluminum Starch Octenylsuccinate (pH 5.5), lotion D contained 3.0% Aluminum Starch Octenylsuccinate and lotion E contained 2.5% of Aluminum Starch Octenylsuccinate (pH 5.3). A total of 103 male and female subjects completed each study, except in the study of lotion D, for which 54(9 male and 45 females) subjects completed the study. No reactions were noted during induction or challenge to lotions A, C, D, and E. One subject developed mild erythema to lotion B after the third induction exposure. It was an isolated incidence. One subject also had a 1 score reaction to lotion B at the 48 h challenge reading of the original exposure site; the erythema resolved by the 96 h scoring. None of the lotions were sensitizers.

**OCULAR IRRITATION STUDIES**

No additional ocular irritation studies were found in the published literature, and unpublished data were not submitted. [Data from the original safety assessment are summarized below.]

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 h after dosing. The test substance produced “very slight transient irritation to the conjunctivae” and was considered to be an “unlikely” ocular irritant in humans.

In an ocular irritation study, two formulations containing 1.0% and 2.5% Aluminum Starch Octenylsuccinate was tested using the chorioallantoic membrane vascular assay (CAMVA). Each lotion was applied to the exposed chorioallantoic membrane (CAM) of ten fertile hen’s eggs. After a 30 minute incubation period, No induced damage was noted to the CAM. The RC50 (the concentration which induced damage in 50% of the eggs) was > 100% and the lotions were considered non-irritating.

The ocular irritation potential of an eyeshadow containing 15% undiluted Aluminum Starch Octenylsuccinate was evaluated in a study involving 6 rabbits. Each product was placed in the unrinsed eye(s) of the rabbits three times. On days 1, 2 and 3 after instillation, the conjunctiva of 1, 3 and 1 rabbit(s) were scored a 2. The ocular irritation potential of a foundation containing 25% of an undiluted Aluminum Starch Octenylsuccinate was evaluated. None of the rabbits that were dosed with the blush had any irritation one day after dosing. One and two days after dosing with the foundation, 4 and 1 rabbit(s), respectively, had a score of 2. The eye irritation potential was considered minimal.
SUMMARY

In 2002, the Panel published a safety assessment of Aluminum Starch Octenylsuccinate with the conclusion that Aluminum Starch Octenylsuccinate is safe as used in cosmetic formulations provided that established limitations imposed on heavy metal concentrations are not exceeded; those limitations were described in the Discussion of that report. Aluminum Starch Octenylsuccinate is the aluminum salt of the reaction product of octenylsuccinic anhydride with starch, and 7 other cosmetic ingredients that are obtained by the reaction of octenylsuccinic anhydride, but have not been reviewed, have been identified, and these ingredients are proposed for inclusion in this re-review.

Frequency of use has increased since the original report was issued. According to 2018 FDA VCRP data, Aluminum Starch Octenylsuccinate is reported to be used in 786 formulations; in 1998, it was reported to be used in 172 formulations. A concentration of use survey is currently being conducted by the Council; these data will be included once they are received. In the original safety assessment, concentration of use data (1998/1999) indicated that Aluminum Starch Octenylsuccinate was used at up to 30% in leave-on products.

No new toxicity data were found in the published literature, and unpublished data were not submitted.

DISCUSSION FROM ORIGINAL REPORT

In the absence of data indicating concentrations of toxic metals that can be found as contaminants in this ingredient, the CIR Expert Panel limited concentrations of the toxic metals in cosmetic-grade Aluminum Starch Octenylsuccinate to the same concentrations as has been established for food-grade modified starches. Thus, cosmetic grade Aluminum Starch Octenylsuccinate must not contain more than 3 mg/kg of arsenic, 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 Chemical 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 200-400 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.
### Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment

<table>
<thead>
<tr>
<th>Ingredient CAS No.</th>
<th>Definition &amp; Structure</th>
<th>Function(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminum Starch Octenylsuccinate 9087-61-0</td>
<td>Aluminum Starch Octenylsuccinate is the aluminum salt of the reaction product of octenylsuccinic anhydride with starch.</td>
<td>Absorbents; Anticaking Agents; Viscosity Increasing Agents - Nonaqueous</td>
</tr>
<tr>
<td>Acacia Seyal Gum Octenylsuccinate 455885-22-0</td>
<td>Acacia Seyal Gum Octenylsuccinate is the product obtained by the reaction of Acacia Seyal Gum with octenylsuccinic acid anhydride.</td>
<td>Surfactants - Emulsifying Agents</td>
</tr>
<tr>
<td>Calcium Starch Octenylsuccinate 374539-60-3</td>
<td>Calcium Starch Octenylsuccinate is the calcium salt of the reaction product of octenylsuccinic anhydride with Zea Mays (Corn) Starch.</td>
<td>Absorbents; Emulsion Stabilizers; Viscosity Increasing Agents - Aquous</td>
</tr>
<tr>
<td>Hydrolyzed Hydroxypropyl Starch Octenylsuccinate</td>
<td>Hydrolyzed Hydroxypropyl Starch Octenylsuccinate is the product obtained by the reaction of octenylsuccinic anhydride with the hydrolysate of Hydroxypropyl Starch derived by acid, enzyme or other method of hydrolysis.</td>
<td>Emulsion Stabilizers; Hair Conditioning Agents; Hair Fixatives; Humectants; Oral Care Agents; Skin-Conditioning Agents - Miscellaneous; Surfactants - Cleansing Agents; Surfactants - Emulsifying Agents; Surfactants - Foam Boosters; Viscosity Increasing Agents - Aquous</td>
</tr>
<tr>
<td>Quinoa Starch Octenylsuccinate</td>
<td>Quinoa Starch Octenylsuccinate is the reaction product of octenylsuccinic anhydride with Chenopodium Quinoa Starch.</td>
<td>Emulsion Stabilizers - Aquous</td>
</tr>
<tr>
<td>Sodium Glycogen Octenylsuccinate</td>
<td>Sodium Glycogen Octenylsuccinate is the sodium salt of the reaction product of octenylsuccinic anhydride with Glycogen.</td>
<td>Skin-Conditioning Agents - Humectant</td>
</tr>
<tr>
<td>Sodium Hydroxypropyl Cyclodextrin Octenylsuccinate</td>
<td>Sodium Hydroxypropyl Cyclodextrin Octenylsuccinate is the sodium salt of the reaction product of Hydroxypropyl Cyclodextrin and octenylsuccinic anhydride.</td>
<td>Deodorant Agents; Emulsion Stabilizers; Humectants; Surfactants - Cleansing Agents; Surfactants - Emulsifying Agents</td>
</tr>
<tr>
<td>Sodium Trehalose Octenylsuccinate</td>
<td>Sodium Trehalose Octenylsuccinate is the sodium salt of the product obtained by the reaction of Trehalose with octenylsuccinic anhydride.</td>
<td>Emulsion Stabilizers; Hair Conditioning Agents; Humectants; Oral Care Agents; Skin-Conditioning Agents - Miscellaneous; Surfactants - Emulsifying Agents</td>
</tr>
</tbody>
</table>

### Table 2. Physical and Chemical Properties of Aluminum Starch Octenylsuccinate

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Form</td>
<td>Powder</td>
<td></td>
</tr>
<tr>
<td>Color</td>
<td>White</td>
<td></td>
</tr>
<tr>
<td>Odor</td>
<td>Faint</td>
<td></td>
</tr>
<tr>
<td>Water Solubility (at 20 °C)</td>
<td>zero</td>
<td></td>
</tr>
<tr>
<td>Other Solubility</td>
<td>Neutral to slightly acidic (aqueous slurry)</td>
<td>15</td>
</tr>
</tbody>
</table>
Table 3. Current and historical frequency and concentration of use according to duration and exposure

<table>
<thead>
<tr>
<th></th>
<th># of Uses</th>
<th>Max Conc of Use (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aluminum Starch Octenylsuccinate</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Totals*</td>
<td>786</td>
<td>172</td>
</tr>
</tbody>
</table>

**Duration of Use**

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Leave-On</td>
<td>744</td>
<td>158</td>
<td>**</td>
</tr>
<tr>
<td>Rinse-Off</td>
<td>42</td>
<td>12</td>
<td>**</td>
</tr>
<tr>
<td>Diluted for (Bath) Use</td>
<td>NR</td>
<td>2</td>
<td>**</td>
</tr>
</tbody>
</table>

**Exposure Type**

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Area</td>
<td>138</td>
<td>11</td>
<td>**</td>
</tr>
<tr>
<td>Incidental Ingestion</td>
<td>32</td>
<td>9</td>
<td>**</td>
</tr>
<tr>
<td>Incidental Inhalation-Spray</td>
<td>14; 122;</td>
<td>3; 13; 17</td>
<td>**</td>
</tr>
<tr>
<td>Incidental Inhalation-Powder</td>
<td>71;115;</td>
<td>55; 17</td>
<td>**</td>
</tr>
<tr>
<td>Dermal Contact</td>
<td>699</td>
<td>159</td>
<td>**</td>
</tr>
<tr>
<td>Deodorant (underarm)</td>
<td>4*</td>
<td>NR</td>
<td>**</td>
</tr>
<tr>
<td>Hair - Non-Coloring</td>
<td>35</td>
<td>2</td>
<td>**</td>
</tr>
<tr>
<td>Hair-Coloring</td>
<td>13</td>
<td>NR</td>
<td>**</td>
</tr>
<tr>
<td>Nail</td>
<td>NR</td>
<td>NR</td>
<td>**</td>
</tr>
<tr>
<td>Mucous Membrane</td>
<td>34</td>
<td>18</td>
<td>**</td>
</tr>
<tr>
<td>Baby Products</td>
<td>1</td>
<td>NR</td>
<td>**</td>
</tr>
</tbody>
</table>

*Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.

** - A concentration of use survey is currently being conducted; these data will be added once they are received.

* It is possible these products are sprays, but it is not specified whether the reported uses are sprays.

b Not specified whether a spray or a powder, but it is possible the use can be as a spray or a powder, therefore the information is captured in both categories.

b It is possible these products are powders, but it is not specified whether the reported uses are powders.

NR – no reported use
REFERENCES


Final Report on the Safety Assessment of Aluminum Starch Octenylsuccinate

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 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 Aluminum 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
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

<table>
<thead>
<tr>
<th>Product category</th>
<th>No. containing ingredient</th>
<th>Concentration of use (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bubble baths (200)</td>
<td>1</td>
<td>—</td>
</tr>
<tr>
<td>Other bath preparations (159)</td>
<td>1</td>
<td>—</td>
</tr>
<tr>
<td>Eyeliner</td>
<td>—</td>
<td>10</td>
</tr>
<tr>
<td>Eye shadow (506)</td>
<td>7</td>
<td>1-30</td>
</tr>
<tr>
<td>Eye lotion (18)</td>
<td>1</td>
<td>1.5-5</td>
</tr>
<tr>
<td>Mascara (167)</td>
<td>2</td>
<td>0.5</td>
</tr>
<tr>
<td>Other eye makeup preparations (120)</td>
<td>1</td>
<td>—</td>
</tr>
<tr>
<td>Powders (247)</td>
<td>16</td>
<td>—</td>
</tr>
<tr>
<td>Other fragrance preparations (148)</td>
<td>1</td>
<td>—</td>
</tr>
<tr>
<td>Hair sprays (aerosol fixatives) (261)</td>
<td>2</td>
<td>—</td>
</tr>
<tr>
<td>Blushers (all types) (238)</td>
<td>8</td>
<td>9-30</td>
</tr>
<tr>
<td>Face powders (250)</td>
<td>39</td>
<td>1-15</td>
</tr>
<tr>
<td>Foundations (287)</td>
<td>15</td>
<td>1-25</td>
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<td>Lipstick (790)</td>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td>Makeup bases (132)</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Other makeup preparations (135)</td>
<td>6</td>
<td>2.5-25</td>
</tr>
<tr>
<td>Deodorants</td>
<td>—</td>
<td>4</td>
</tr>
<tr>
<td>Other personal cleanliness products (291)</td>
<td>7</td>
<td>—</td>
</tr>
<tr>
<td>Aftershave lotion (216)</td>
<td>5</td>
<td>1.5-5</td>
</tr>
<tr>
<td>Other shaving preparation products (60)</td>
<td>2</td>
<td>—</td>
</tr>
<tr>
<td>Skin cleansing (cold creams, cleansing lotions, liquids, and pads)</td>
<td>—</td>
<td>2</td>
</tr>
<tr>
<td>Face and neck skin care (excluding shaving) (263)</td>
<td>2</td>
<td>0.5-2</td>
</tr>
<tr>
<td>Body and hand skin care (excluding shaving) (796)</td>
<td>15</td>
<td>1.5-10</td>
</tr>
<tr>
<td>Moisturizing creams, lotions, powders, and sprays (769)</td>
<td>6</td>
<td>1-5</td>
</tr>
<tr>
<td>Night creams, lotions, powders, and sprays</td>
<td>—</td>
<td>1-3</td>
</tr>
<tr>
<td>Paste masks (Mud packs) (255)</td>
<td>3</td>
<td>1-6</td>
</tr>
<tr>
<td>Other skin care preparations (692)</td>
<td>14</td>
<td>5</td>
</tr>
<tr>
<td>Suntan gels, creams, and liquids (136)</td>
<td>2</td>
<td>—</td>
</tr>
<tr>
<td>Indoor tanning preparations (62)</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Other suntan preparations (38)</td>
<td>2</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total for 1998</strong></td>
<td><strong>172</strong></td>
<td></td>
</tr>
</tbody>
</table>
ex 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 in the absence 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 used at levels that are now current and in the manner now practiced, uncertainties exist requiring that additional studies be conducted.”

**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 corn starch as an emulsifying agent. Increased urine concentrations of glutarate and 2-ketogluartate 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.

**TABLE 2**

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

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

*No further details given for the two limits on lead.
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, \(\sim 70 \text{ mg}\)) 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 RC50 (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 unriused 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 unriused. 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 Octenylsucinate was nontoxic to rats by in-
halation (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 pos-
sible 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 us-
ingen 9 or 10 "sensitive skin" panelists. Occlusive patches were
applied for two consecutive 24-hour periods. Neither lotion in-
duced 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
(pH 4.0) containing 1.0% (w/w) Aluminum Starch Octenylsuc-
cinate; 104 of 135 male and female panelists completed the study.
Clinical Research Services (1996) studied lotion C (pH 5.5) con-
taining 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) con-
taining 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 (unre-
lated 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 lo-
tions A, C, D, and E. One subject developed "mild erythema"
(scored 1, the lowest nonzero score) to lotion B after the third in-
duction exposure. It was an isolated incidence. One subject also
had a score 1 reaction to lotion B at the 48-hour challenge read-
ing 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 pan-
elists. 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 consid-
ered 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 sam-
pies (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 anticing 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.

REFERENCES


2 Available for review: Director, Cosmetic Ingredient Review, 1101 17th St, NW, Suite 310, Washington, DC 20036-4702, USA.
Biosearch, Inc. 1994. Human repeated insult patch test: Lotion A containing 1.0% aluminum starch octenylsuccinate. Study 93-7939H. Unpublished data submitted by CTFA. (23 pages.)


Clinical Research Services. 1996. Human repeated insult patch test: Lotion E containing 2.5% aluminum starch octenylsuccinate. Study C96-0002. Unpublished data submitted by CTFA. (33 pages.)


Cosmetic, Toiletry and Fragrance Association (CTFA). 1996. Closed patch test: Lotion C containing 2.5% aluminum starch octenylsuccinate. Study 96-28-SPG by unknown laboratory. Unpublished data submitted by CTFA. (3 pages.)

CTFA. 1997. Closed patch test: Lotion C containing 2.23% aluminum starch octenylsuccinate. Study 97-54-SPG by unknown laboratory. Unpublished data submitted by CTFA. (10 pages.)


CTFA. 1998b. Concentration of use data on Aluminum Starch Octenylsuccinate dated 11/18/98. (1 page.)

CTFA. 1998c. Repeat Insult Patch Test dated 11/16/98. (3 pages.)


CTFA. 1999b. Concentration of use data. 4/28/99. (4 pages.)

CTFA. 1999c. Three eye irritation studies. 1/27/99 (3 pages.)

CTFA. 1999d. Three allergic contact sensitization tests. 1/27/99 (20 pages.)


Food Research Laboratories. 1950b. Allergenicity test with dry flow: Aluminum starch octenylsuccinate. Unpublished data submitted by CTFA. (4 pages.)


Skin Study Center. 1995. Chamber scarification test: Lotion A containing 1.0% aluminum starch octenylsuccinate. Study 3681. Unpublished data submitted by CTFA. (23 pages.)


## 2018 FDA VCRP RAW DATA

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<th>CATEGORY</th>
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<td>ALUMINUM STARCH OCTENYL SUCCINATE</td>
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<td>03A - Eyebrow Pencil</td>
<td>ALUMINUM STARCH OCTENYL SUCCINATE</td>
<td>5</td>
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<td>03B - Eyeliner</td>
<td>ALUMINUM STARCH OCTENYL SUCCINATE</td>
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<td>03C - Eye Shadow</td>
<td>ALUMINUM STARCH OCTENYL SUCCINATE</td>
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<tr>
<td>03D - Eye Lotion</td>
<td>ALUMINUM STARCH OCTENYL SUCCINATE</td>
<td>13</td>
</tr>
<tr>
<td>03F - Mascara</td>
<td>ALUMINUM STARCH OCTENYL SUCCINATE</td>
<td>7</td>
</tr>
<tr>
<td>03G - Other Eye Makeup Preparations</td>
<td>ALUMINUM STARCH OCTENYL SUCCINATE</td>
<td>23</td>
</tr>
<tr>
<td>04C - Powders (dusting and talcum, excluding aftershave talc)</td>
<td>ALUMINUM STARCH OCTENYL SUCCINATE</td>
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<td>04E - Other Fragrance Preparation</td>
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<td>05B - Hair Spray (aerosol fixatives)</td>
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<tr>
<td>05F - Shampoos (non-coloring)</td>
<td>ALUMINUM STARCH OCTENYL SUCCINATE</td>
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<tr>
<td>05G - Tonics, Dressings, and Other Hair Grooming Aids</td>
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<tr>
<td>05I - Other Hair Preparations</td>
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<td>06B - Hair Tints</td>
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<td>06E - Hair Color Sprays (aerosol)</td>
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<td>06H - Other Hair Coloring Preparation</td>
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<tr>
<td>07A - Blushers (all types)</td>
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<tr>
<td>07B - Face Powders</td>
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<td>07C - Foundations</td>
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<td>07E - Lipstick</td>
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<td>07F - Makeup Bases</td>
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<td>07G - Rouges</td>
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<td>07H - Makeup Fixatives</td>
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<td>10A - Bath Soaps and Detergents</td>
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<td>10B - Deodorants (underarm)</td>
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<td>Other Personal Cleanliness Products</td>
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<td>11A</td>
<td>Aftershave Lotion</td>
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<td>11D</td>
<td>Preshave Lotions (all types)</td>
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<td>11G</td>
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<td>Cleansing</td>
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<td>Face and Neck (exc shave)</td>
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<td>Body and Hand (exc shave)</td>
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<td>Foot Powders and Sprays</td>
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<td>Night</td>
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<td>Paste Masks (mud packs)</td>
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<td>Other Skin Care Preps</td>
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<td>Suntan Gels, Creams, and Liquids</td>
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<td>Indoor Tanning Preparations</td>
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<td>Other Suntan Preparations</td>
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