Amended Safety Assessment of Acacia Senegal Gum and Acacia Senegal Gum Extract as Used in Cosmetics

Status: Tentative Amended Report for Public Comment

Last Panel Review: September 8-9, 2025

Release Date: October 3, 2025

All interested persons are provided 60 days from the above release date (i.e., by **December 2, 2025**) to comment on this safety assessment, and to identify additional published data that should be included or provide unpublished data which can be made public and included. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient. All unpublished data submitted to CIR will be discussed in open meetings, will be available for review by any interested party and may be cited in a peer-reviewed scientific journal. Please submit data, comments, or requests to the CIR Executive Director, Dr. Bart Heldreth.

The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; David E. Cohen, M.D.; Samuel E. Cohen, M.D., Ph.D.; Curtis D. Klaassen, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D., and the Senior Director is Monice Fiume, M.B.A. This safety assessment was prepared by Regina Tucker, M.S., former Scientific Analyst/Writer, and Thushara Diyabalanage, Ph.D., former Scientific Analyst/Writer, CIR.

ABBREVIATIONS

BCOP bovine corneal opacity and permeability

CFR Code of Federal Regulations colony forming units

CIR Cosmetic Ingredient Review
Council Personal Care Products Council

Dictionary web-based International Cosmetic Ingredient Dictionary and Handbook

DMH 1,2-dimethylhydrazine DSS dextran sodium sulfate

EFSA European Food Safety Authority
EPA Environmental Protection Agency
FDA Food and Drug Administration
FEV forced expiratory volume
GRAS generally recognized as safe

HET-CAM hen's egg test on the chorioallantoic membrane HPLC high-performance liquid chromatography

IgE immunoglobulin E IVIS in vitro irritation score

 LD_{50} lethal dose for 50% of the population

LOQ limit of quantification

MoCRA Modernization of Cosmetics Regulation Act

MTT 3-[4,5-dimethylthiazol-2yl]-2,5-diphenyltetrazolium bromide

NOAEL no-observed-adverse-effect-level

OECD Organisation of Economic Co-operation and Development

Panel Expert Panel for Cosmetic Ingredient Safety

PBS phosphate buffered saline PCB polychlorinated biphenyl

PCDD polychlorinated dibenzo-p-dioxins
PCDF polychlorinated dibenzofurans
RLD Registration and Listing Data
SLS sodium lauryl sulfate

SPT skin prick test

TGFβ1 transforming growth factor β1

US United States

USDA United States Department of Agriculture

UV ultraviolet

VCRP Voluntary Cosmetic Registration Program WHO-TEQ World Health Organization-toxic equivalent

ABSTRACT

The Expert Panel for Cosmetic Ingredient Safety (Panel) reassessed the safety of Acacia Senegal Gum and Acacia Senegal Gum Extract, which are reported to function as adhesives and binders in cosmetics. Industry should minimize impurities, such as heavy metals and pesticide residues, according to limits set by the US Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA). The Panel reviewed the relevant data to determine the safety of these ingredients, and issued an amended report reaffirming the original conclusion that Acacia Senegal Gum and Acacia Senegal Gum Extract are safe in cosmetics in the present practices of use and concentration described in this safety assessment.

INTRODUCTION

According to the web-based *International Cosmetic Ingredient Dictionary and Handbook (Dictionary*), Acacia Senegal Gum is reported to function in cosmetics as an adhesive, binder, emulsion stabilizer film former and fragrance ingredient; no function is reported for Acacia Senegal Gum Extract. These ingredients were first reviewed as part of a larger group of ingredients derived from several species of the acacia plant. In 1998, the Expert Panel for Cosmetic Ingredient Safety (Panel) issued a final report with an insufficient data conclusion for the entire group of 11 acacia ingredients, including Acacia Senegal Gum and Acacia Senegal Gum Extract. Subsequently, the Panel's data needs were met for Acacia Senegal Gum and Acacia Senegal Gum Extract, but none of the other acacia-derived ingredients (including Acacia Senegal Extract, now named Acacia Senegal Flower/Stem Extract according to the *Dictionary*), and an amended final report was published in 2005. At that time, the Panel concluded that Acacia Senegal Gum and Acacia Senegal Gum Extract are safe as used in cosmetic based on the animal and clinical data included in that report. (Both of these reports are available on the Cosmetic Ingredient Review (CIR) website (https://cir-reports.cir-safety.org/).)

In accordance with its Procedures, the Panel evaluates the conclusions of previously issued reports approximately every 15 years, and it has been at least 15 years since this assessment has been issued. In September 2023, the Panel determined that this safety assessment should be re-opened due to increases in frequency and concentration of use and new product category usage in baby products, and to reassess the risks of immunoglobulin E (IgE)-mediated hypersensitivity caused by these ingredients.

Botanicals, such as *Acacia senegal*, may contain hundreds of constituents. In this assessment, the Panel is evaluating the potential toxicity of each of Acacia Senegal Gum and Acacia Senegal Gum Extract as a whole, complex substance; toxicity from single components might not predict the potential toxicity of botanical ingredients.

This safety assessment includes relevant published and unpublished data that are available for each endpoint that is evaluated. Published data are identified by conducting an extensive search of the world's literature; a search was last conducted in August 2025. A listing of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints that the Panel typically evaluates, is provided on the CIR website (https://www.cir-safety.org/supplementaldoc/ preliminary-search-engines-and-websites; https://www.cir-safety.org/supplementaldoc/cir-report-format-outline). Unpublished data are provided by the cosmetics industry, as well as by other interested parties. Please no te that because the other ingredients included in the larger group had an insufficient data conclusion, they are not included in the review.

Excerpts of data from the previous report on the acacia-derived ingredients that are relevant to Acacia Senegal Gum and Acacia Senegal Gum Extract are disseminated throughout the text of this re-review document, as appropriate, and are identified by italicized text. (This information is not included in the tables or the summary section.)

The cosmetic ingredient names, according to the *Dictionary*, are written as depicted in the title of this report, without italics and without abbreviations. When referring to the genus and species from which the ingredients are derived, the standard taxonomic practice of using italics is followed (i.e., *Acacia senegal*). Often in published literature, the general names acacia, acacia gum, and gum arabic are used, and it is not known how the substance being tested compares to the ingredient as used in cosmetics. Therefore, if it is not known whether the substance being discussed is equivalent to the cosmetic ingredient, the test substance will be identified by the name used in the publication that is being cited (which is the case throughout most of this report, as well as in the data excerpted from the previous report). However, if it is known that the substance is a cosmetic ingredient, the naming convention provided in the *Dictionary* (e.g., Acacia Senegal Gum) will be used.

CHEMISTRY

Definition and Plant Identification

According to the *Dictionary*, Acacia Senegal Gum (CAS No. 9000-01-5) is the dried, gummy exudate obtained from plant *Acacia senegal*; the accepted scientific name for *Acacia senegal* is *Senegalia senegal*. Acacia Senegal Gum is often referred to as gum arabic in the published literature. Acacia Senegal Gum Extract is defined as the extract of the gum of the acacia, *Acacia senegal*.

Structurally, gum arabic is an arabinogalactan-protein complex composed of magnesium, calcium, and potassium salts of arabic acid. The structure of arabic acid is made of 1,3-linked β -D-galactopyranosyl units along with branches that consist of two to five β -D-galactopyranosyl residues linked together via 1,3-ether linkages and connected to the fundamental β -D-galactopyranosyl chain by 1,6-linkages. The main component of this gum (approximately 90%) is an arabinogalactan fraction with a molecular weight 250 kDa. 5,6 A example structure of this fraction is drawn in Figure 1.

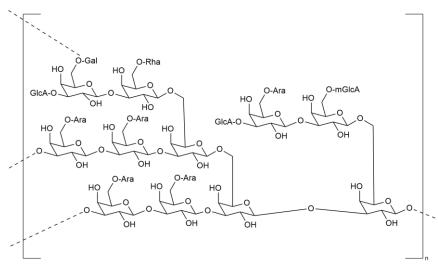


Figure 1. An example arabinogalactan faction (Gal is galactose; Rha is rhamnose; Ara is arabinose; GlcA is glucouronic acid; and mGlcA is 4-O-methyl-D-glucouronic acid)

The minor component of the gum consists of hydrophobic proteins with a molecular weight range of 1000 - 2000 kDa. This protein part is associated with polysaccharide part via covalent bonds at hydroxy proline, serine and threonine amino acid units. It is postulated that this glycosyl part of the protein component of the acacia gum provides the amphiphilic units and ultimately the surface activity. This highly-branched nature in its structure has given it a high solubility.

Upon further investigations conducted using high-performance size exclusion chromatography, multi-angle laser light scattering, single-angled x-ray scattering, synchrotron radiation circular dichroism and transmission electron microscopy, the glycoprotein molecular structure has been elucidated as mixture of spheroidal monomers and more anisotropic oligomers.⁷ These studies have shown that the molecular architecture of Acacia Senegal Gum is an assembly of ring-like glycoproteins modules which have been explained as hydroxyproline and arabinogalactan subunits.

Glycosylphosphatidylinositol lipid units are also present in acacia gum structure. These lipid units are composed of saturated fatty acids (C_{22} - C_{25}) some of which are hydroxylated at the second carbon.⁶ The glycosyl component is oligosaccharide in nature.

Chemical Properties

Gum arabic is a pale white to orange-brown solid which breaks with a glassy fracture. The best grades are in the form of spheroidal tears of varying size with matte surface texture. When ground, the resultant pieces are paler and have a glassy appearance. Additional chemical properties are listed in Table 1.

Method of Manufacture

Gum arabic is produced when the Acacia tree is stressed by infection, poor nutrition, heat, or lack of moisture.³ The gum exudes through wounds in the bark that occur naturally or are purposely made to stimulate production. The exudate dries rapidly, is collected as hardened drops or tears, sorted, graded, and marketed. The gum becomes harder during storage. The removal of the bark that adheres to the tears is critical to the production of quality gum arabic.

Acacia gum is in the form of tears or nodules when it is collected from the trees.⁶ It then undergoes sorting and grading based on their color and impurities. The gum which is light in color is considered best in quality. It can deteriorate during storage due to the presence of enzymes. Therefore, the deterioration is prevented by temperature control during the storage period.

Raw gum is a blend of gum nodules with different mesh sizes, containing vegetable and mineral impurities and fluctuating bacteriological contamination.5 The level of impurities can be reduced slightly using dry purifications steps, such as kibbling, sieving and pulverization. Kibbling is a mechanical treatment of nodules or tears for the preparation of acacia gum powder of different particle/mesh size. This kibbled gum has more solubility as compared to nodules or tears of acacia gum. For the preparation of food grade acacia gum, the best quality gum nodules are selected. However, the bacteriological contamination cannot be improved, and often raw gum does not meet the specifications for acacia gum.

The dry methods of purification have been substituted by purification in an aqueous solution as they have proven to be more efficient. The gum is fully dissolved in water and all the impurities removed by a cascade of filtration steps reducing the levels of insoluble matter in the finished product (as low as 0.02%). Bacterial contamination is also reduced by treatment in a heat exchanger plate and the gum syrup is concentrated and dried, reducing the level of microbial contamination in the powder not more than 0.05 colony-forming units per gram (cfu/g).

Different processes are used for recovering purified, powdered Acacia Senegal Gum from the syrup. Roller-drying is used to produce gum in powder form with good hydration properties. However, the drastic thermal treatment employed at the drying step can have undesirable effects which reduce emulsifying properties. Spray drying has been able to address this successfully to retain good physical and functional properties. The spray drying techniques have been further improved by using a multi-stage spray drying process where fine particles of gum produced during drying are recycled at the top of the dryer. Agglomerated gum

particles are obtained, keeping the entire properties of the raw gum, but containing no dust or particles below 75 μ m and giving unique hydration and dissolution properties, without any lump formation up to the maximum level of solubility in water of 45 - 50%.

Composition/Impurities

Three grades of gum arabic have been noted in the published literature: (1) processed gum arabic recovered by spray-drying from a solution of commercial food-grade gum arabic after filtration to remove sand, and after heat treatment to effect pasteurization; (2) finely powdered natural gum arabic of poor commercial quality, giving solutions of a dark reddish-brown color; (3) finely powdered natural gum arabic of very high quality, giving essentially colorless solutions.³

Acacia gum contains galactose (37 – 53%), arabinose (20 – 30%), rhamnose (10 – 16%), glucouronic acid (6 – 14%), 4-*O*-methyl-D-glucouronic acid (1.5%), and protein 2%.⁶ According to a documentation provided to the European Food Safety Authority (EFSA), the protein content was in a range of 0.99 - 2.7% in three samples analyzed in duplicate.⁵ The principal amino acids found in acacia gum arabic is hydroxy proline, serine, aspartic, glycine and leucine.⁶

The protein fraction in acacia gum is known to contain oxidizing enzymes, particularly oxidases and peroxidases which may oxidize some secondary metabolites present in the gum.⁵ In fact, it is thought that the oxidation of amines and phenols may form the colored compounds. However, it has been noted that heating acacia gum to a high temperature during manufacturing may destroy these enzymes before the start of their actions.

According to *United States Pharmacopeia* monographs, *acacia* has following specifications: loss on drying (15% maximum); arsenic (3 ppm); lead (0.001%), heavy metals (0.004%).¹⁰

Five batches each of two acacia gum exudates were analyzed (after hydrolysis) for molar distribution of the sugars. Galactose was in the range 28.3 - 37.1%, arabinose 31.7 - 53.6%, rhamnose 1.9 - 16.3%, and glucuronic acid 5.3 - 16.3%. The same batches showed also concentrations of arabinogalactoprotein in the range 6.8 - 36.9%, and concentrations of arabinogalactan plus glycoprotein fraction ranging from 63.1 - 93.2%; the molecular weights varied between 373,000 and 1.071,100 Da.

During an analysis of five additional batches acacia gum (gum arabic) for impurities and contaminants, lead concentration varied between < 0.02 (limit of quantification (LOQ)) and 0.036 mg/kg; mercury, cadmium and arsenic were below the respective LOQs. ¹¹ Aluminum concentration was in the range 3.7-14.7 mg/kg, iron 3.2-16.5 mg/kg, copper 1.1-1.59 mg/kg, and zinc and tin below the respective LOQs. Presence of mycotoxin ochratoxin A, in acacia gum (gum arabic) was below the LOQ ($0.5~\mu$ g/kg in four batches and $0.02~\mu$ g/kg in one batch). Aflatoxins B1, B2, G1 and G2 were detected at $< 0.01~\mu$ g/kg (all of them in four batches) and $< 0.02~\mu$ g/kg (one batch). The sum of polychlorinated dibenzo-p-dioxins (PCDDs) and polychlorinated dibenzo-furans (PCDFs) was in the range of 0.032-0.13 ng PCDD/F World Health Organization polychlorinated dibenzo-p-dioxins and furans toxic equivalence (WHO-TEQ)/kg, dioxin-like polychlorinated biphenyls (PCBs) were in the range 0.015-0.06 ng WHO-TEQ/kg, and the sum of dioxins and dioxins-like PCBs in the range 0.047-0.19 ng PCDD/F + PCB WHO-TEQ/kg. The pesticides were not detected in a multiresidue analysis (> 30 compounds of different groups). Escherichia coli (in 5 g) and Salmonella spp. (in 25 g) were absent in all the batches.

The chemical composition of a sample of gum acacia dissolved in water was determined via high-performance liquid chromatography (HPLC). The results showed the presence of a variety of phenolic compounds and flavonoids. The major phenolic compounds were identified as p-coumaric and ferulic acid (10.14 μ g/ml and 11.09 μ g/ml, respectively), and the major flavonoid was luteolin (10.22 μ g/ml). The results obtained using HPLC are also shown in Table 2.

UV Absorption

An increase in absorbance for Acacia Senegal was observed between 400 nm and approximately 260 nm, reaching a plateau at wavelengths ranging from 270 to ~250 nm.³ A rapid increase in absorbance was observed at wavelengths less than 250 nm. UV absorption spectra provided on two other lots of Acacia gum (Acacia Senegal) were both similar to the preceding UV spectral analysis.

The UV absorption spectrum of a mixture (202 μ g/ml) containing Acacia Senegal Gum (51 - 59%) was submitted.¹³ It was observed that the absorbance over the wavelength range 290 - 700 nm was negligible.

USE

Cosmetic

The safety of the cosmetic ingredients addressed in this assessment is evaluated based on data received from the US FDA and the cosmetics industry on the expected use of Acacia Senegal Gum and Acacia Senegal Gum Extract in cosmetics. Data included herein were obtained from the FDA and the Personal Care Products Council (Council), and it is these values that define the present practices of use and concentration that are assessed by the Panel. Responses to a survey conducted by the Council indicate maximum reported concentrations of use. Frequency of use data were obtained from the FDA Voluntary Cosmetic Registration Program (VCRP) database and from Registration and Listing Data (RLD). As a result of the Modernization of Cosmetics Regulation Act (MoCRA) of 2022, the VCRP was discontinued in 2023 and, as of 2024, manufacturers and processors are required to register facilities and list their products (and ingredients therein) with the FDA (i.e., RLD). An exception is made for small businesses (average gross annual sales in the US of cosmetic products for the previous 3-yr period is less than \$1,000,000, adjusted for inflation), which are exempt from MoCRA reporting for most cosmetic product categories. Eye area products,

injected products, internal use products, or products that alter appearance for more than 24 h, and the facilities that manufacture these products, are not included in this exemption. ¹⁴ Please note, at this time, it is not appropriate to contrast data from the VCRP and RLD to determine a trend in frequency of use because there are numerous differences in the ways the data for the VCRP and the RLD were collected and processed, and because reporting frequency of use is now mandatory (as opposed to the past practice of voluntary reporting). Although the VCRP program is now defunct, trends in frequency of use from the RLD alone are not yet possible in that a baseline is currently not available.

According to RLD submitted to CIR in 2024, Acacia Senegal Gum is used in 1833 formulations, and Acacia Senegal Gum Extract in 92 formulations (Table 3). According to 2023 VCRP survey data, Acacia Senegal Gum and Acacia Senegal Gum Extract were reported to be used in 287 and 9 formulations, respectively. In 2001, Acacia Senegal Gum had 1 use reported in the VCRP, and Acacia Senegal Gum Extract was not reported to be used. The results of the concentration of use survey conducted by the Council in 2025 reported that Acacia Senegal Gum has a maximum reported concentration of use 4% in mascaras and in eye lash and eye brow preparation products. In 2000, the greatest maximum reported concentration of use of Acacia Senegal Gum was 9% in mascara.

Acacia Senegal Gum was reported to be used in baby products in 2023 according to the VCRP, but no baby product uses were reported in the RLD submitted in 2024, and no concentrations of use in baby products were reported. Cosmetic products containing these ingredients may incidentally come in contact with the eyes (e.g., up to 4% Acacia Senegal Gum in mascara and eyelash and eyebrow preparations), and they are used in products that could be incidentally ingested and come in contact with mucous membranes (e.g., up to 2.9 % Acacia Senegal Gum in other oral hygiene products).

Acacia Senegal Gum and Acacia Senegal Gum Extract are used in cosmetic formulations that may be sprays and powders and could possibly be inhaled; for example, according to RLD, Acacia Senegal Gum and Acacia Senegal Gum Extract are used in 1 and 5 hair spray formulations, at 0.19% and concentration not reported, respectively, and Acacia Senegal Gum is reported to be used in 21 face powder formulations (concentration of use not provided). In practice, as stated in the Panel's respiratory exposure resource document (https://www.cir-safety.org/cir-findings), most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and tracheobronchial regions and would not be respirable (i.e., would not enter the lungs) to any appreciable amount. 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.

Some products containing Acacia Senegal Gum and Acacia Senegal Gum Extract may be marketed for use with airbrush delivery systems. With the advent of MoCRA and the current product categories outlined by the FDA, it is now mandatory that cosmetic products used in airbrush delivery systems be reported as such for some, but not all, product categories in the RLD. In other words, a reliable source of frequency of use data regarding the use of cosmetic ingredients in conjunction with airbrush delivery systems is now available, in some instances. Some of the reported product categories for these ingredients as listed in the RLD do require designation if airbrush application is used, and this type of application was reported (e.g., leg and body paints). Additionally, the Council currently surveys the cosmetic industry for maximum reported use concentrations of ingredients in products which may be used in conjunction with an airbrush delivery system; thus, this type of data may also be available when submitted. Please note that no concentration of use data were provided indicating airbrush application. Nevertheless, no consumer habits and practices data or particle size data are publicly available to evaluate the exposure associated with this use type, thereby preempting the ability to evaluate risk or safety. Without information regarding the consumer habits and practices data or product particle size data (or other relevant particle data, e.g., diameter) related to this use technology, the data profile is incomplete, and the Panel is not able to determine safety for use in airbrush formulations. Accordingly, the data are insufficient to evaluate the exposure resulting from cosmetics applied via airbrush delivery systems.

Non-Cosmetic

Gum arabic is a direct food substance generally recognized as safe (GRAS) under the provisions of Section 184.1330 of the Code of Federal Regulations (CFR). It is approved for use in various food categories at the following maximum permitted usage levels (21CFR184.1330) and (21CFR172.780): 2.0% (beverage and beverage bases), 5.6% (chewing gum), 12.4% (confections and frostings), 1.3% (dairy product analogs), 1.5% (fats and oils), 2.5% (gelatins, puddings, and fillings), 46.5% (hard candy and cough drops), 8.3% (nuts and nut products), 6.0% (quiescently frozen confection products), 4.0% (snack foods), 85.0% (soft candy), and 1% (all other food categories).

Uses of Acacia Senegal Gum in the various food categories include emulsifier and emulsifier salt, flavoring agent and adjuvant, formulation aid, stabilizer and thickener, humectant, surface-finishing agent, processing aid, microencapsulating agent and powder. Acacia Senegal Gum is used in the food, textile, pottery, lithography, and pharmaceutical industries.^{6,18}

TOXICOKINETIC STUDIES

Absorption, Distribution, Metabolism, and Excretion (ADME)

Animal

Oral

In a study using rats, an apparent decrease in the caloric value of gum arabic with increasing administered dose was noted. gum arabic was incorporated into the diet at concentrations of 5, 10, and 17%. Digestibility data indicated that up to 80% of the gum arabic was absorbed. Following a 48-h fast, 20 young male rats were fed 10 mg of a mixture consisting of 34% white,

powdered gum arabic and 66% cacao butter. The difference in glycogen content between the rats who were fed gum arabic, and the rats in the control did not show a significant difference. It was concluded that gum arabic was not metabolized by enzymes of the rat digestive tract. The metabolism of gum arabic was evaluated using albino Wistar male rats. One group of animals was fed standard diet only, and the other diet plus 200 g gum arabic/kg, ad libitum, for 4 wk. In rats fed gum arabic in their diet, a white flocculent precipitate typical of gum arabic was detected in contents from the stomach and small intestine, but not from the cecum, distal colon, or in the feces. This suggests that the metabolism of gum arabic is mediated by bacteria in the cecum. In animals in which the cecum was resected, precipitable gum arabic was detected along the length of the entire residual intestine. This observation suggests that in the absence of the bacterial mass resident in the cecum, there is no degradation of gum arabic. No precipitate typical of gum arabic was found in the gastrointestinal tract of the control rats that received only the standard diet. In a guinea pig study, it was determined that gum arabic was highly digestible (90%) when administered in the diet at a concentration of 15% for 10 d.

Human

Oral

In a study with 22 infants, 1 to 15-mo-old, that were given gum arabic (15 to 20 g/d) in milk, no evidence of absorption was found.³ Additionally, no urinary excretion of pentose or significant excretion of gum arabic was observed in the stools. The excretion of gum arabic and its effect on glucose absorption and routine hematological and biochemical measurements in 5 healthy male volunteers (30 to 55-yr-old) was examined. No significant effect on the mean concentration of serum lipids, mean blood glucose concentration, or mean insulin concentration was noted; a significant decrease in serum cholesterol was observed.

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

Oral

In an acute oral toxicity study using rabbits (weights and strain not stated), an LD₅₀ of 80 g/kg gum arabic was reported.³

Short-Term Toxicity Studies

Animal

Oral

The oral toxicity of gum arabic (dose not stated) using Sprague-Dawley rats (16 males, 16 females) was assessed.³ The animals were fed the test article daily for 28 d. No treatment-related behavioral effects were noted. All values for serum chemistry and mean red blood cell volume were within the normal range. No toxicologically significant lesions were noted at microscopic examination. Wistar albino rats (number of rats not stated) were fed 10% (w/w) gum arabic daily for 45 d. Portions of the jejunum, ileum, and cecum were excised and the ultrastructure of each was evaluated using transmission electron microscopy. No abnormalities in organelles were observed within cells of the jejunum, ileum, or cecum. No significant ultrastructural differences occurred between experimental and control rats. Groups of rats (number and weights not stated) were fed 15% gum arabic in the diet for 62 d. A cathartic effect was noted. Weight gain, feed efficiency, hematological findings, and organ weights were normal. Diet containing 15-20% gum arabic was fed to 133 guinea pigs for 3 - 9 wk. No toxic effects resulted from the administration of gum arabic.

<u>Human</u>

Oral

Five healthy male subjects (30 to 55-yr-old) ingested 25 g gum arabic daily for 21 d.³ Toxic effects were not observed during the 21-d period. The fact that gum arabic was not recovered from the feces suggested that it is degraded extensively in in the human colon.

Subchronic Toxicity Studies

Oral

The oral toxicity of gum arabic was examined in two experiments using albino Wistar rats.³ In the first experiment, test groups of 15 male and 15 female rats were fed 0.91-8.6% and 0.75-7.5% gum arabic, respectively, for 13 wk. In the second experiment, groups of 15 male and 15 female rats were fed gum arabic at an average concentration of 18.6 and 18.1%, respectively, for 13 wk. No differences or alterations were found that were attributable to the ingestion of gum arabic. The only treatment-related alteration noted at necropsy was cecal enlargement in rats of the highest dose group. In another study, 4 groups of 5 male albino Wistar rats were fed diets containing 0.5, 1.5, 2.5, and 3.5% (w/w) gum arabic daily for 91 d. Electron microscopy reported no abnormalities in cardiac muscle or the liver.

In a 90-d oral toxicity study, male and female F344/DuCrj rats (6 animals/sex/group) were administered a diet containing gum arabic, a naturally processed polysaccharide exudate from gum acacia trees (*Acacia senegal*), at doses of 0, 1.25, 2.5 and 5.0% in feed (equivalent to 770, 1505, and 3117 mg/kg bw/d for males, respectively, and 839, 1666, and 3296 mg/kg bw/d, respectively for females). The treatment diet was mixed with an irradiated powder diet. Animals were observed daily. Weight, urinalysis, and hematological and histopathological examinations were all carried out. At the end of week 13, all rats were euthanized. During the 90 d on the diet no clinical signs of effect of toxicity were noted in any of the treated animals. Overall, the study results indicated no adverse effects on any parameter examined. The no-observed-adverse-effect-level (NOAEL was determined to 3117 mg/kg bw/d for males and 3296 mg/kg bw/d for females.

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY STUDIES

Oral administration of gum arabic did not cause antifertility effects in female rats or the suppression of spermatogenesis in male rats.³ Gum arabic was not teratogenic when administered orally to mice at doses up to 1600 mg/kg. Oral doses of gum arabic up to 1600 mg/kg also were not teratogenic in rats (days 6-15 of gestation) and hamsters (days 6-10 of gestation), and oral doses up to 800 mg/kg were not teratogenic in rabbits (days 6-18 of gestation). No fetal malformations were observed when rats were given 5% gum arabic solution orally (days 6-17 of gestation in one study; 14 d prior to mating, throughout mating, and until day 21 of gestation in another); additionally, no effects on estrus cycle were observed went he test article was given pre-mating through lactation. Gum arabic, at a concentration of 15%, failed to induce teratogenicity or other reproductive effects in female rats. Gum arabic 30% also did not cause abnormal sperm development in rats s. Embryotoxicity was not noted in mice injected intraperitoneally with a 1% aqueous suspension or mucilage prepared from gum arabic.

Oral

A study was conducted to examine the effects of gum arabic (*Acacia senegal*) on male fertility.²⁰ Groups of 1 male and 2 female Balb/c mice were given with tap water or 5% (w/v) gum arabic in tap water (5 g/100 ml) for 21 d. Two weeks after the females delivered, blood was obtained from the males for testosterone measurements by immunoassay for the quantitative determination of testosterone. The males were then killed and the testes were removed and examined. The number of living offspring was higher in the test group than the controls. The testosterone concentration was statistically significantly greater in the test group (1.35 ng/ml) compared to the controls (0.85 ng/ml). Histopathological analysis showed the gum arabic group had normal seminiferous tubules with increased spermatogenesis.

GENOTOXICITY STUDIES

In Vitro

Gum arabic was not mutagenic in numerous in vitro mutagenicity tests using Salmonella typhimurium, Saccharomyces cerevisiae, and Bacillus subtilis bacterial strains.³ In an in vitro cytogenetics assay, though results were classified as slightly positive, gum arabic did not induce definite abnormal anaphase figures in diploid human embryonic lung (WI-38) fibroblasts (test methods not given). The mutagenicity of gum arabic was also evaluated in numerous in vivo assays, the results of which were mostly negative. However, statistically significant positive results were noted in one of the three dominant lethal tests (rat assay, but not in two mouse assays) that were performed. Further testing in the mouse heritable translocation test yielded negative results. In acute and short-term in vivo cytogenetics assays (rats), though no significant positive responses were observed, there may have been a slight positive response. It was stated that further tests and a detailed statistical evaluation are needed in order to confirm this possibility. Negative results were also reported in micronucleus tests (mouse bone marrow smears) dosed intraperitoneally with 3% gum arabic and in other in vivo assays.

CARCINOGENICITY STUDIES

Oral

The carcinogenicity of gum arabic was studied using F344 rats (50 males, 50 females) and B6C3F1 mice (50 males, 50 females) in a 2-yr study. Both male and female rats were divided into high- and low-dose groups. Low-dose animals were fed gum arabic at a concentration of 25,000 ppm in the diet and high-dose animals were fed 50,000 ppm for 103 wk, followed by 1-2 wk of basal diet. The control mice (50 males and 50 females) and rats (50 males and 50 females) were given the basal diet according to the same schedule. The investigators concluded that gum arabic was not carcinogenic in F344 rats or B6C3F1 mice of either sex.

Parenteral

No evidence of carcinogenicity was observed in rats dosed intraperitoneally with gum arabic (1.75 or 7.0% in saline or water) 3x/wk for up to 15 wk. ³ In another study, tumors were not observed in guinea pigs injected intramediastinally with 0.1 ml of a gruel of gum arabic (single dose).

Co-Carcinogenicity

Gum arabic has been reported to have increased the number of metastases in mice injected intraperitonially with Ehrlich ascites carcinoma cells.³ The carcinoma cells were injected 6 or 24 h after the mice were injected with gum arabic intravenously. However, it was noted that ascites tumor formation was inhibited under the same conditions.

ANTI-CARCINOGENICITY STUDIES

The ability of gum arabic to reduce induced colorectal carcinogenesis were studied by investigating the effect of gum arabic on the formation of aberrant crypts, local, hepatic and systemic genotoxicity and oxidative stress.²¹ Colorectal carcinogenesis was induced in Swiss male mice which were then given water or 2.5 or 5% gum arabic via gavage 5 ml/kg for 12 wk. Proximal and distal colon, liver, blood, and bone marrow samples were obtained. The number of aberrant crypts in the of gum arabic-treated animals was lower than in the control groups.

In a study to investigate the effect of gum arabic (from *Acacia senegal*) on colonic tissues, a group of mice was treated with 10% wt/vol gum arabic in drinking water, and gene array was performed.²² Chemical carcinogenesis was induced by intraperitoneal injection of 20 mg/kg 1,2-dimethylhydrazine (DMH) followed by 3 cycles of 3% dextran sodium sulfate (DSS) in drinking water with or without gum arabic treatment for 7 d, followed by distilled water for subsequent 14 d (one cycle - 21 d).

Within 4 d, dosing with gum arabic (10% wt/wt) in drinking water decreased the colonic transcript levels of the angiogenetic factors angiogenin 1 (by 78%), angiogenin 3 (by 88%), and angiogenin 4 (by 92). According to Western blotting, gum arabic treatment also decreased angiogenin protein expression, and based on immunohistochemistry, ss-catenin expression was also decreased. Chemical carcinogenesis resulted in multiple colonic tumors in untreated groups within 12 wk; treatment with gum arabic in drinking water significantly decreased the number of tumors by 70%.

OTHER RELEVANT STUDIES

Immunological Effects

A study was conducted to evaluate the anti-inflammatory and antifibrotic effects of gum arabic in treating ulcerative colitis.²³ DSS was used to induce colitis in C57BL/6 mice and the animals were then switched to normal drinking water to monitor recovery. Mice received 140 g/l gum arabic before (pre-gum arabic treated group) or after (post-gum arabic treated group) induction of colitis. Disease activity and recovery were assessed by changes in body weight, disease activity index, and histological assessment. Gene expressions of proinflammatory, anti-inflammatory, and fibrotic markers were measured in colonic tissues.

Mice in the pre-gum arabic treated group showed an increase in body weight, with no differences in disease activity index scores, during the recovery phase and had lower histological colitis scores than mice in the post-gum arabic group, which showed higher disease activity scores and histological scores during the recovery phase. During the recovery phase, mice in the pre-gum arabic treated group showed increased expression of proinflammatory markers, while gene expression of the fibrotic markers, transforming growth factor $\beta 1$ (TGF $\beta 1$) and procollagen I, were reduced. The reduced fibrotic marker expression was associated with reduced collagen staining and increased epithelial cell proliferation. The researchers concluded that administration of gum arabic had protective and alleviative effects on the severity of DSS-induced colitis, with a reduction in colonic fibrosis and TGF $\beta 1$ expression.

Effect on Cisplatin-Induced Infertility

The co-treatment effect of gum acacia/arabic (*Acacia senegal*) on cisplatin-related spermatogenesis dysfunction was investigated. ¹² Cisplatin has several harmful effects on spermatogenesis. Daily administration of aqueous gum acacia/arabic, 7.5 mg/kg orally via a stomach tube, alleviated the adverse effects of cisplatin on spermatogenesis and reversed testicular damage, reduced oxidative stress induced by cisplatin, elevated testosterone and luteinizing hormone levels in blood sera, elevated germ cells, and ameliorated sperm quality.

DERMAL IRRITATION AND SENSITIZATION STUDIES

Sensitization

The skin sensitization potential of a mascara containing 8.0% Acacia Senegal was evaluated in the maximization test using 28 healthy adult volunteers.³ It was concluded that, under the conditions of the test, the mascara containing 8.0% Acacia Senegal did not possess a detectable contact-sensitizing potential and is not likely to cause contact sensitivity reactions under normal use conditions.

OCULAR IRRITATION STUDIES

Details on ocular irritation studies summarized below can be found in Table 4.

Potential ocular irritancy of mascaras containing 1% Acacia Senegal Gum²⁴ and 3% Acacia Senegal Gum Extract²⁵ was investigated in EpiOcular[™] assays; both formulations were predicted to be non-irritant.²⁴ The ocular irritation potential of a mixture of Acacia Senegal Gum (51 - 59%) studied by bovine corneal opacity and permeability test method, was not classified for eye irritation or serious eye damage.¹³.A hen's egg test on the chorioallantoic membrane (HET-CAM) was performed for this test material indicated that the test item was non-irritant.¹³ An in vitro cytotoxicity assay by neutral red uptake performed on cell model fibroblasts by human skin (ATTC-CRL-2703) showed no ocular irritation potential of a mascara containing 2.9% Acacia Senegal Gum.²⁶ The results of a bovine corneal opacity and permeability assay and a neutral red release assay conducted on a mascara containing 6% Acacia Senegal Gum indicated that it was well-tolerated.²⁷

In a clinical study conducted with 20 subjects, a mascara containing 2.9% Acacia Senegal Gum was applied to the periocular area, at least 1x/d for 1 mo.²⁸ No significant alteration of palpebral skin and mucosa were noticed. In another clinical study performed on 29 subjects for a 4-wk use period with a mascara containing 6% Acacia Senegal Gum, good ocular and peri-ocular acceptability were reported.²⁹ Ocular irritation potential of a mascara with 3% Acacia Senegal Gum Extract was evaluated in 50 female subjects.³⁰ The product was applied at least 5 times/wk for 4 wk and a potential to elicit an ophthalmic irritation was not observed. It was well tolerated by subjects who were contact lens wearers and who had self-perceived sensitive eyes.

CLINICAL STUDIES

Case Reports

A number of case reports of gum arabic allergenicity have been identified in the published literature.³ Positive skin reactions were observed in 10 subjects who ingested gum arabic. The results of serologic studies (sera from 4 subjects) indicated that gum arabic was the dominant gum antigen in 2 subjects. Cross-reactivity between gum arabic and gum tragacanth was reported for a 24-yr old patient who developed sensitization to Quillaja bark (Quillaja saponaria) dust which led to rhinitis and asthma.

In the case reports of exposures to gum arabic, a skin prick test (SPT) was performed for initial diagnosis and if positive for IgE, generally it was followed by testing for sIgE specific to gum arabic. 18,31-33 Food workers in direct contact with gum arabic on a regular basis also showed allergic symptoms. These case reports are summarized in Table 5.

Further analysis of the immunological reaction of gum arabic showed that the sensitization to its carbohydrate structural components occur casually in atopic patients with pollen sensitization without apparent exposure to the gum. ¹⁸ The study suggested that the allergy to gum arabic is mediated preferentially by IgE antibodies directed to its polypeptide chain.

SUMMARY

According to the *Dictionary*, Acacia Senegal Gum is reported to function in cosmetics as an adhesive, binder, emulsion stabilizer film former, and fragrance ingredient; no function is reported for Acacia Senegal Gum Extract. These ingredients were first reviewed in 1998 as part of a larger group of ingredients derived from the acacia plants. At that time, the Panel issued a final report with an insufficient data conclusion for the entire group of 11 acacia ingredients, including Acacia Senegal Gum and Acacia Senegal Gum Extract. Subsequently, data were submitted that met the data needs for Acacia Senegal Gum and Acacia Senegal Gum Extract; in the amended report that was published in 2005, the Panel concluded that Acacia Senegal Gum and Acacia Senegal Gum Extract are safe as used in cosmetic products.

In accordance with its Procedures, the Panel evaluates the conclusions of previously issued reports approximately every 15 years, and it has been at least 15 years since this assessment has been issued. In September 2023, the Panel determined that this safety assessment should be re-opened in order to reassess the risks of IgE-mediated sensitivity caused by these ingredients and due to increases in frequency and concentration of use and new product category usage in baby products.

According to RLD submitted to CIR in 2024, Acacia Senegal Gum is used in 1833 formulations and Acacia Senegal Gum Extract in 92 formulations. Responses to the Council survey conducted in 2025 indicate that Acacia Senegal Gum was reported to be used at up to 4% in mascara and in eye lash and eyebrow preparations.

Male and female F344/DuCrj rats (6 animals/sex/group) were fed a diet containing 0, 1.25, 2.5, and 5.0% (equivalent to 770, 1505, and 3117 mg/kg bw/d for males, respectively, and 839, 1666, and 3296 mg/kg bw/d, respectively for females). The NOAEL was determined to be 3117 mg/kg/d for males and 3296 mg/kg/d for females.

In a study in which groups of 1 male and 2 female Balb/c mice were dosed with tap water or 5% (w/v) gum arabic in tap water (5 g/100 ml) for 21 d, the number of living offspring was higher in the test group than the controls. Compared to controls, the testosterone concentration was statistically significantly greater and seminiferous tubules showed increased spermatogenesis in the male given gum arabic.

Treatment with gum arabic at concentrations of 2.5 and 5% reduced the formation of aberrant crypts in the colon of mice. In another study, gum acacia led to marked down regulation of several angiogenins and further genes relevant for tumor growth.

In a study examining the effect of gum arabic on ulcerative colitis, administration of gum arabic to mice had protective and alleviative effects on the severity of DSS-induced colitis, with a reduction in colonic fibrosis and $TGF\beta1$ expression. Administration of gum acacia/arabic alleviated spermatogenesis and reversed testicular damage, reduced oxidative stress induced by cisplatin, elevated testosterone and luteinizing hormone levels in blood sera, elevated germ cells, and ameliorated sperm quality.

Potential ocular irritancy of mascaras containing 1% Acacia Senegal Gum and 3% Acacia Senegal Gum Extract was investigated in EpiOcular™ assays; both formulations were predicted to be non-irritant. The ocular irritation potential of a mixture of Acacia Senegal Gum (51 - 59%) was evaluated using the bovine corneal opacity and permeability test; the test article was not classified for eye irritation or serious eye damage. A HET-CAM assay that was performed for this test material indicated that the test item was non-irritant An in vitro cytotoxicity assay by neutral red uptake performed on cell model fibroblasts by human skin (ATTC-CRL-2703) showed no ocular irritation potential of a mascara containing 2.9% Acacia Senegal Gum The results of a bovine corneal opacity and permeability assay and a neutral red release assay conducted on a mascara containing 6% Acacia Senegal Gum indicated that it was well-tolerated.

In a clinical study conducted with 20 subjects, a mascara containing 2.9% Acacia Senegal Gum was applied to the periocular area, at least 1x/d for 1 mo. No significant alteration of palpebral skin and mucosa were noticed. In another clinical study performed on 29 subjects for a 4-wk use period with a mascara containing 6% Acacia Senegal Gum, good ocular and peri-ocular acceptability were reported. Ocular irritation potential of a mascara with 3% Acacia Senegal Gum Extract was evaluated in 50 female subjects. The product was applied at least 5 times/wk for 4 wk and a potential to elicit an ophthalmic irritation was not observed. It was well tolerated by subjects that were contact lens wearers and who had self-perceived sensitive eyes.

Cases of food workers in direct contact with gum arabic on a regular basis having allergic symptoms have been reported. In one study, analysis of the immunological reaction of gum arabic showed that the sensitization to its carbohydrate structural components occur casually in atopic patients with pollen sensitization without apparent exposure to the gum, and allergy to gum arabic is mediated preferentially by IgE antibodies directed to its polypeptide chain.

DISCUSSION

In accordance with its Procedures, the Panel re-evaluates the conclusions of previously-issued reports approximately every 15 years. In 1998, the Panel published a final report on 11 acacia ingredients, including Acacia Senegal Gum and Acacia Senegal Gum Extract, and concluded that the available data were insufficient to determine safety of the acacia ingredients. Subsequently, the Panel's data needs were met for Acacia Senegal Gum and Acacia Senegal Gum Extract, and a Final Amended Report was published in 2005. At the September 2023 meeting, since more than 15 years have passed since the last review, the Panel considered another re-review and determined to reopen the safety assessment due to the increases in frequency and concentration of use and new product category usage in baby products. The Panel also wanted to reassess the risk of IgE mediated sensitivity caused by these ingredients; however, the Panel observed that the reports of IgE responses to these ingredients are rare, and that almost all that do occur are occupational and related to exposure to high concentrations. Accordingly, the Panel concluded that both ingredients are safe in cosmetics in the present practices of use and concentration described in this safety assessment.

The Panel found that a robust data profile was available for Acacia Senegal Gum. Also, the Panel noted that gum arabic is a direct food substance that is GRAS, particularly noting the maximum permitted usage level of 85% in soft candy, and Acacia Senegal Gum is often referred to as gum arabic in the published literature. Although the profile of Acacia Senegal Gum Extract was not as robust, the Panel stated that the safety of the two ingredients was likely equivalent.

Aflatoxin has been detected in *Acacia senegal*, and accordingly, the Panel stated that aflatoxin should be minimized in Acacia Senegal Gum and Acacia Senegal Gum Extract. The Panel has adopted the limits set by the US Department of Agriculture (USDA) corresponding to "negative" aflatoxin content. The Panel also expressed concern about heavy metals, pesticide residues, and other plant species that may be present in botanical ingredients. They stressed that the cosmetics industry should continue to minimize impurities in cosmetic formulations according to limits set by the US FDA and the EPA.

The Panel discussed the issue of incidental inhalation exposure resulting from these ingredients (e.g., hair sprays and other fragrance preparations). Inhalation toxicity data were not available. However, the Panel noted that in aerosol products, the majority of droplets/particles would not be respirable to any appreciable amount. Furthermore, droplets/particles deposited in the nasopharyngeal or tracheobronchial regions of the respiratory tract present no toxicological concerns based on the chemical and biological properties of these ingredients. Coupled with the small actual exposure in the breathing zone and the low concentrations at which these ingredients are used in potentially inhaled products, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects. A detailed discussion and summary of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at https://www.cir-safety.org/cir-findings

The Panel's respiratory exposure resource document (see link above) notes that airbrush technology presents a potential safety concern. Although frequency and/or concentration of use data are now available (and in some cases mandated) for ingredients marketed for use with airbrush delivery systems in certain product categories, no data are available for consumer habits and practices thereof, product particle size, or other relevant particle data (e.g., diameter). As a result of deficiencies in these critical data needs, the data profile is incomplete, and the safety of cosmetic ingredients applied by airbrush delivery systems cannot be determined by the Panel. Accordingly, the Panel has concluded the data are insufficient to support the safe use of cosmetic ingredients applied via an airbrush delivery system.

CONCLUSION

The Expert Panel for Cosmetic Ingredient Safety concluded that Acacia Senegal Gum and Acacia Senegal Gum Extract are safe in cosmetics in the present practices of use and concentration described in this safety assessment.

TABLES

Table 1. Chemical properties of Acacia Senegal Gum

Property	Value	Reference
Physical Form	solid which breaks with a glassy fracture	9
Color	Pale white to orange-brown	9
Molecular Weight (kDa)	330-940	6
UV absorption	negligible absorbance at 290 - 700 nm (mixture containing 51 – 59% Acacia Senegal Gum)	13
Specific Gravity	1.35-1.49	
Viscosity (ml/g)	16-24	6
Optical rotation	-34 to -37	8
Water Solubility	Readily soluble	6
Other Solubility	Insoluble in alcohol	6

Table 2. Composition of secondary metabolites in Acacia Senegal Gum^{12}

Acacia Senegal Gum	-		
Phenolic Compounds	Concentration (ug/ml)	Flavonoid Compounds	Concentration (ug/g)
chlorogenic acid	7.88	7-OH flavone	6.11
catechol	3.45	naringin	9.14
syringenic	3.56	rutin	7.02
p-coumaric	10.14	quercetin	6.88
cinnamic acid	9.79	kaempferols	3.88
caffeic acid	3.69	luteolin	10.22
pyrogallol	9.77	apigenin	2.33
gallic acid	2.56	catechin	1.98
protoatechulic	2.31		
ferulic acid	11.09		
salicylic acid	2.17		
ellagic acid	3.09		
benzoic acid	4.19		

Table 3. Frequency (RLD/VCRP) and concentration of use according to likely duration and exposure and by product category

	Acacia Senegal Gum					Acacia Senegal Gum Extract				
	# of Uses				lax Conc of Use		# of Uses		Max Conc	
	RLD (2024) ¹⁵	VCRP (2023) ¹⁶	VCRP (2001) ³	% (2025) ¹⁷	% (2000) ³	RLD (2024) ¹⁵	VCRP (2023) ¹⁶	VCRP (2001) ³	% (2025) ¹⁷	% (2000)
Totals*	1833	287	1	0.00005-4	0.0001-9	92	9	NR	0.000005 -0.041	0.001
summarized by likely duration and exposure**										
Duration of Use										
Leave-On	***	210	1	0.00005 - 4	0.0001-9	***	5	NR	0.0000005 -0.021	NR
Rinse-Off	***	66	NR	0.00005 - 3.4	NR	***	4	NR	0.021-0.041	0.001
Diluted for (Bath) Use	***	11	NR	NR	NR	***	NR	NR	0.005	NR
Exposure Type		,	•		•	•	'	•		
Eye Area	***	80	1	0.15 - 4	1-9	***	1	NR	NR	NR
Incidental Ingestion	***	2	NR	0.24 - 2.9	NR	***	NR	NR	0.000005	NR
Incidental Inhalation-Spray	***	57ª, 44 ^b	NR	0.19-0.42; 0.003 - 0.2 ^a ; 0.00005-3 ^b	0.0001ª	***	3 ^b	NR	0.021 ^b	NR
Incidental Inhalation-Powder	***	4, 44 ^b , 3 ^c	NR	0.00005 -3b	0.5	***	3ь	NR	0.021 ^b	NR
Dermal Contact	***	200	NR	0.00005 - 4	0.02-3	***	6	NR	0.005-0.041	0.001
Deodorant (underarm)	***	NR	NR	NR	NR	***	NR	NR	NR	NR
Hair - Non-Coloring	***	14	NR	0.000075 - 0.2	0.0001	***	1	NR	0.021	NR
Hair-Coloring	***	NR	NR	NR	NR	***	1	NR	0.021	NR
Nail	***	NR	NR	NR	NR	***	NR	NR	0.001	NR
	***	<u> </u>	Ī	i		***		i	i	
Mucous Membrane	***	43	NR	0.003 - 2.9	NR	***	1	NR	0.000005 -0.041	0.001
Baby Products	***	3	NR	NR	NR	***	NR	NR	NR	NR 16
as reported by product category		:				•				16
Baby Products				.						
Baby Lotions/Oils/Powders/Creams	NR	3	NR	NR	NR					
Bath Preparations	5									
Bath Oils, Tablets, and Salts	2	10	NR	NR	NR					
Bubble Baths	1	1	NR	NR	NR					
Bath Capsules						NR	NR	NR	0.005	NR
Other Bath Preparations	2	NR	NR	NR	NR					
1	703	INIX	INK	INK	INIX	2				
Eye Makeup Preparations (not children's)	10	ND	NR	NR	1	2] !	
Eyebrow Pencil		NR 1		0.44	3					
Eyeliner	36	1	NR		. i				ļ	
Eye Shadow	33	1	NR	NR	NR					
Eye Lotion	7	1	NR	0.37	NR					
Eye Makeup Remover	1	NR	NR	NR	NR					
False Eyelashes	2	NA	NA	NR	NA					
Mascara	555	71	1	0.15 - 4	3 - 9	1	1	NR	NR	NR
Eyelash and Eyebrow Adhesives, Glues, and Sealants	1	NA	NA	NR	NA					
Eyelash and Eyebrow Preparations (primers,	40	NA	NA	2.5 - 4	NA	1	NA	NA	NR	NA
conditioners, serums, fortifiers)										
Other Eye Makeup Preparations	38	6	NR	NR	NR					
Children's Eye Makeup Preparations	1									
Other Children's Eye Makeup	1	NA	NA	NR	NA					
Fragrance Preparations	1									
Powders (dusting/talcum, excl aftershave talc)	NR	NR	NR	NR	0.5					
Other Fragrance Preparation	1	NR	NR	0.42	NR			•		
Hair Preparations (non-coloring)	225			V	1 111	37				
Hair Conditioners	3 (l.o); 95 (r.o)	2	NR	0.003 (l.o); 0.0005 (r.o)	NR	1 (l.o), 9 (r.o)	NR	NR	0.021 (r.o)	NR
Hair Sprays (aerosol fixatives)	1	NR	NR	0.0003 (1.0)	NR	5	NR	NR	NR	NR

Table 3. Frequency (RLD/VCRP) and concentration of use according to likely duration and exposure and by product category

	Acacia Senegal Gum					Acacia Senegal Gum Extract				
		# of Uses	-	Max Conc	of Use		# of Uses		Max Con	c of Use
	RLD (2024) ¹⁵	VCRP (2023) ¹⁶	VCRP (2001) ³	% (2025) ¹⁷	% (2000) ³	RLD (2024) ¹⁵	VCRP (2023) ¹⁶	VCRP (2001) ³	% (2025) ¹⁷	% (2000) ³
Hair Straighteners	2	1	NR	NR	NR					
Rinses (non-coloring)	4	NR	NR	NR	NR	4	NR	NR	NR	NR
Shampoos (non-coloring)	1 (l.o.): 79 (r.o)	5	NR	0.000075 (r.o.)	NR	5 (r.o)	1	NR	0.021 (r.o)	NR
Tonics, Dressings, and Other Hair Grooming Aids	24	4	NR	0.003 - 0.2	0.0001	4	NR	NR	NR	NR
Other Hair Preparations	20 (l.o) 28 (r.o)	2	NR	0.04 (l.o.; not spray)	NR	6 (l.o); 15 (r.o)	NR	NR	NR	NR
Hair Coloring Preparations	6			1 7 /		27				
Hair Rinses (coloring)						NR	1	NR	NR	NR
Hair Bleaches	4	NR	NR	NR	NR	1	NR	NR	NR	NR
Other Hair Coloring Preparation	2 (1.0)	NR	NR	NR	NR	26 (r.o)	NR	NR	0.021 (1.0)	NR
Makeup Preparations (not eye; not children's)	237									
Blushers and Rouges (all types)	6	1	NR	NR	NR					
Face Powders	21	4	NR	NR	NR					
Foundations	133 (traditional		NR	0.44 (traditional	NR					
1 ouncerons	application)		1,110	application)	1110					
Leg and Body Paints	10 (traditional application); 2 (airbrush)	1	NR	NR	NR					
Lipstick and Lip Glosses	33	NR	NR	0.3	NR	NR	NR	NR	0.000005	NR
Makeup Bases	9 (traditional application)	NR	NR	NR	NR					
Makeup Fixatives	5	NR	NR	NR	NR					
Makeup Preparations for Children (not eye)	9									
Children's Face Paints	8	NA	NA	NA	NA					
Children's Face Powders	1	NA	NA	NA	NA					
Other Children's Makeup	2	NA	NA	NA	NA					
Manicuring Preparations	1	1121	1171	1111	1121					
Nail Polish and Enamel	1	1	NR	NR	NR					
Other Manicuring Preparations	1	1	TVIC	l IVIC	IVIC	NA	NR	NR	0.001	NR
Oral Products	6			ļ		11/1	IVIX	INIC	0.001	IVIC
Dentifrices	2	NR	NR	2.9	NR					
Other Oral Hygiene Products	4	2	NR	0.24	NR					
Personal Cleanliness	35		INK	0.24	INK	2				
Bath Soaps and Body Washes	17	26	NR	0.003 - 0.052	NR	1	NR	NR	0.041	0.001
Deodorants (underarm)	7	NR	NR NR	NR	NR NR	1	NIV.	NIV.	0.041	0.001
Other Personal Cleanliness Products	4 (l.o); 7 (r.o)	4	NR NR	NR NR	NR NR	1 (1.0.)	1	NR	NR	NR
	2	4	INK	INK	NIC	1 (1.0.)	1	NK.	NK	INK
Shaving Preparations		ND	ND	0.020	ND					
Aftershave Lotions	NR 1	NR NR	NR NB	0.028	NR NB					
Shaving Soaps (cakes, sticks, etc.)	1	. .	NR NB	NR NB	NR NB					
Other Shaving Preparation Products	1	1	NR	NR	NR					
Skin Care Preparations	598	10		2.4) ID	23	4) II	N.D.	
Cleansing	66	12	NR	3.4	NR	14	1	NR	NR	NR
Depilatories	6	NR	NR	NR	NR		_			
Face and Neck (excluding shaving preparations)	303 (l.o); 48 (r.o)	43	NR	0.17 - 3 (l.o); 0.00006 (r.o) (both not spray)	NR	15 (l.o); 1 (r.o)	3	NR	NR	NR
Body and Hand (excluding shaving preparations)	28 (l.o); 7 (r.o)	1	NR	0.00005 (l.o.; not spray)	NR	2 (l.o); 1 (r.o)	NR	NR	NR	NR
Moisturizing	137	46	NR	0.0055 - 0.083	NR	15	NR	NR	NR	NR
Night	17	6	NR	0.0055	NR					

Table 3. Frequency (RLD/VCRP) and concentration of use according to likely duration and exposure and by product category

	Acacia Senegal Gum				Acacia Senegal Gum Extract					
	# of Uses			Max Conc	of Use	# of Uses		Max Conc		c of Use
	RLD (2024) ¹⁵	VCRP (2023) ¹⁶	VCRP (2001) ³	% (2025) ¹⁷	% (2000) ³	RLD (2024) ¹⁵	VCRP (2023) ¹⁶	VCRP (2001) ³	% (2025) ¹⁷	% (2000) ³
Paste Masks (mud packs)	21	13	NR	0.00005 - 3.3	NR					
Skin Fresheners	9	NR	NR	NR	NR					
Other Skin Care Preparations	53 (l.o); 17 (r.o)	11	NR	0.63 (l.o)	0.02	2 (l.o.)	1	NR	NR	NR
Suntan Preparations	5					1				
Suntan Gels, Creams, and Liquids	2	1	NR	0.26 (not spray)	NR					
Indoor Tanning Preparations	5 (traditional application)	NR	NR	NR	NR	1 (traditional application)	1	NR	NR	NR
Other Preparations (i.e., those preparations that do not fit another category)	23	NA	NA	NR	NA	10	NA	NA	NR	NA

NR – not reported; NA – not applicable (this category was not part of the VCRP)

l.o. – leave-on; r.o. – rinse-off

^{*}The total FOU provided for RLD refers to the ingredient count supplied by FDA, and is not a summation of the number of uses per category because each product may be categorized under multiple product categories. For data supplied via the VCRP or by the Council survey, the sum of all exposure types may not equal the sum of total uses because each ingredient may be used in cosmetics with multiple exposure types.

**Likely duration and exposure are derived from VCRP and survey data based on product category (see Use Categorization https://www.cir-safety.org/cir-findings)

^{***} In the RLD each ingredient may be reported under several product categories, making a summation of RLD misleading in comparison to VCRP data. Accordingly, RLD are presented below by product category (as supplied by FDA), but are not summarized by likely duration and exposure.

^{****}at the time of the YEAR safety assessment, concentration of use data were not reported by the FDA, and a concentration of use survey was not conducted; YYYY data were presented in the original assessment and are reported here [if applicable]

^a 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

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

Table 4. Ocular irritation studies

	Vehicle		Test			Reference
Test Article		Concentration/Dose	Population	Protocol	Results	
			IN VITRO			
1% Acacia Senegal Gum in mascara	None	Neat	EpiOcular™ human cell construct	EpiOcular™ assay Duration of exposure to result 50% decrease in MTT conversion in the test article related-human cell construct was determined	50% toxicity was not observed in 12.9 h, longest possible exposure. Non-ocular irritant	24
2.9% Acacia Senegal Gum in a mascara	Culture medium	0.03 - 2 mg/ml	Cell model fibroblasts by human skin (ATTC-CRL- 2703)	In vitro cytotoxicity assay by neutral red uptake	Non-ocular irritant	26
Mascara containing 6% Acacia Senegal Gum	none	neat	Isolated bovine cornea	BCOP and neutral red release assay	Well tolerated	27
mixture of Acacia Senegal Gum (51 - 59%)	0.9% NaCl	20%	Isolated bovine cornea	BCOP in accord with OECD TG 437. Test material left in contact with isolated corneas for 4 h.	In Vitro Irritancy score (IVIS) was -2.2. Non-ocular irritant.	13
Acacia Senegal Gum (51-59%)	None	Neat	chorion-allantoic membrane of fertilized Leghorn hens' eggs	НЕТ-САМ.	Non-ocular irritant	13
Mascara containing 3% Acacia Senegal Gum Extract	none	Neat	EpiOcular™ human cells construct	EpiOcular™ assay Topical application ocular irritation screening assay to determine 50% decrease of MTT		25
			HUMAN			
Mascara containing 2.9% Acacia Senegal Gum	none	neat	20 subjects; 50% wearing contact lenses)	Applied on periocular area, at least once a day for 1 mo.	No significant alteration or palpebral skin and mucosa were noticed.	28
Mascara containing 6% Acacia Senegal Gum	none	neat	29 subjects	4-wk use study	Good ocular and peri-ocular acceptability reported	29
Mascara with 3% Acacia Senegal Gum Extract	none	neat	54 subjects; 50% had self-perceived sensitive eyes and 50% wore contact lenses	In-use test. Product was applied at least 5 times per wk for 4 wk.	No ophthalmic irritation	30

Table 5. Case reports of occupational exposures to gum arabic

Description	Reference
-Eight male employees aged 23-52 yr were exposed to a powder mixture composed of 10% thaumatin and 90% gum arabic, which led to allergic symptoms in the upper airways. -Three individuals with rhinitis but without lower respiratory symptoms underwent spirometric and plethysmographic testing. SPT were performed. Anterior rhinoscopy was used to assess the state of the turbinates. A positive SPT for pure thaumatin was obtained in all 4 individuals with rhinitis of whom also had a positive skin prick test result for pure gum arabic and gum arabic -specific IgE (sIgE).	32
In 2002 a 30-yr-old male pharmaceutical industry worker was admitted for medical advice after experiencing workplace-related shortness of breath, chest tightness, runny nose, itching, swelling, redness of the eyes and redness of the face and neck. He was exposed to dust from a variety of drugs and additives in the tablet coating plant that he worked in and in 1994 his symptoms began to worsen. -Symptoms occurred mainly during weighing of gum arabic or another substance at his workplace. The case was studied further to identify stage-binding components responsible for the work-related symptoms. -SPT was performed with gum arabic (1% w/v, protein concentration 40 μg/ml; material from the patient's workplace) and a panel of environmental allergens. SPT with extracts of materials from the patient's workplace in PBS showed negative reactions, with the exception of gum arabic which produced a 4 mm wheal/20 mm flare with the 1% (w/v) extract and a 2 mm wheal/8 mm flare with a diluted 0.1% (w/v) extract. Total IgE was 80 kU/l. Lung function and challenge tests were performed. Nebulizations were performed for 0.6 s during each of 10 slow total lung capacity preaths with doubling concentrations up to 10 mg gum arabic/ml (maximal cumulative dose 0.45 mg; this corresponds to a maximal protein dose of 1.8 μg/ml). After the bronchial challenge with gum arabic, the patient complained of chest tightness. A 36% decrease in FEV 1 from 3,690 to 2,340 ml PBS) was documented 10 min after the maximal dose-The study showed that gum arabic may cause occupational allergic rhinitis and asthma with urticaria symptoms in some patients	18
19 patients (control) underwent SPT with gum arabic (1% w/v, protein concentration 40 ug/ml; material from the patients' workplace) and nvironmental allergens. Thirty-six subjects with total IgE ≥ 100 kU/l or at least 1 positive SPT were tested for IgE to gum arabic. Additionally, the sera of 7 highly topic patients without occupational exposure to gum arabic were selected to complete the control group for in vitro tests. Only 3 subjects showed slgE to gum arabic: one control with positive SPT, one control with negative SPT, and the patient that came to the linic. it appeared that the allergy to gum arabic is mediated preferentially by IgE antibodies directed to its polypeptide chain	18
Eleven candy factory workers with respiratory and/or skin symptoms referred to the hospital reported some of the following symptoms: hives, erythema of the hands, dyspnea, rhinitis, eye symptoms, redness of the skin, itching of the skin, cough, nasal congestion, and secretion. Six candy factory workers had occupational allergic disease, in which 4 of the cases were confirmed to be occupational asthma caused by gum arabic with contact urticaria. Contact urticaria was verified in 2 of the workers via cutaneous exposure test. One worker underwent a specific bronchial provocation test to gum arabic and was found to be positive.	31
A 35-yr-old male presented with a 5-yr history of recurrent bilateral nasal obstruction; since the previous year, it had been followed by the onset of wheals on his arms. His job involved making candies with gum arabic. SPTs were performed with 10% wt/vol gum arabic in physiological saline, yielding a 9-mm wheal. Open patch testing was performed by applying 10% wt/vol gum arabic in saline solution on his back and leaving it under occlusion for 20 min; this also produced multiple wheals. ImmunoCAP tests resulted in positive results at a level of 0.33 kU/l. The level of total IgE was 85 kU/l. A nasal provocation test with (200 AU/ml) gave a positive result.	33

REF<u>ERENCES</u>

- 1. Nikitakis J, Kowcz A. 2025. wINCI: International Cosmetic Ingredient Dictionary and Handbook. https://incipedia.personalcarecouncil.org/winci/. Date Accessed: January 8, 2025.
- Cosmetic Ingredient Review. 1998. Safety Assessment of Acacia Catechu, Acacia Concinna, Acacia, Concinna Extract, Acacia Dealbata, Acacia Dealbata Extract, Acacia Decurrens, Acacia Decurrens Extract, Acacia Farnesiana, Acacia Farnesiana extract, Acacia Senegal, Acacia Senegal Extract, and Acacia Senegal Gum Extract. [Available from CIR: (https://cir-reports.cir-safety.org/)].
- 3. Andersen FA, (ed). Final Report of the Safety Assessment of Acacia Catechu Gum, Acacia Concinna Fruit Extract, Acacia Dealbata Leaf Extract, Acacia Dealbata Leaf Wax, Acacia Decurrens Extract, Acacia Farnesiana Extract, Acacia Farnesiana Flower Wax, Acacia Farnesiana Gum, Acacia Senegal Extract, Acacia Senegal Gum, and Acacia Senegal Gum Extract. *Int J Toxicol*. 2005;24(Suppl 3):75–118.
- 4. Al-Jubori Y, Ahmed NTB, Albusaidi R, Madden J, Das S, Sirasanagandla SR. The efficacy of gum arabic in managing diseases: A systematic review of evidence-based clinical trials. *Biomolecules (Basel, Switzerland)*. 2023;13(1):138.
- 5. EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), Mortensen A, Aguilar F, et al. Re-evaluation of acacia gum (E 414) as a food additive. *EFSA J.* 2017;15(4):e04741.
- 6. Mudgil D, Mudgil S. Acacia gum: Chemistry, properties & food applications. Food and Humanity. 2024;2:100264.
- 7. Renard D, Lepvrier E, Garnier C, Roblin P, Nigen M, Sanchez C. Structure of glycoproteins from Acacia gum: An assembly of ring-like glycoproteins modules. *Carbohydrate polymers*. 2014;99:736–747.
- 8. Jurasek P, Phillips GO, Varga S, Chikamai BN, Banks WB. The classification of natural gums.VI. Gum arabic derived from *Acacia senegal* var. Kerensis from Kenya. *Food Hydrocolloids*. 1994;8(6):567–88.
- 9. Joint FAO/WHO Expert Committee on Food Additives 1997. Gum arabic. https://www.fao.org . Date Accessed: January, 2025.
- 10. USP NF Monographs Acacia http://www.pharmacopeia.cn/v29240/usp29nf24s0_m100.html. Date Accessed: January 10, 2025.
- 11. EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Bampidis V, Azimonti G, et al. Safety and efficacy of a feed additive consisting of acacia gum (gum Arabic) for all animal species (A.I.P.G. Association for International Promotion of Gums). EFSA J. 2022;20(4):e07252.
- 12. Nofal AE, Okdah YA, Rady MI, Hassaan HZ. Gum Acacia attenuates cisplatin toxic effect spermatogenesis dysfunction and infertility in rats. *Int J Biol Macromol.* 2023;240:124292.
- 13. Anonymous 2025. Information on Acacia Senegal Gum (UV Absorption and Ocular Irritation) [Unpublished data submitted by the Personal Care Products Council on April 17, 2025].
- 14. Federal Food and Drug, and Cosmetic Act (FD&C Act), Section 612.
- 15. U.S. Food and Drug Administration Office of the Chief Scientist. 2024. Registration and Listing Data Frequency of Use of Cosmetic Products. College Park, MD [Obtained under the Freedom of Information Act from the Division of Freedom of Information; as requested as "Frequency of Use Data" July 17, 2024; received July 30, 2024].
- 16. US Food and Drug Administration Center for Food Safety & Applied Nutrition. 2023. Voluntary Cosmetic Registration Program Frequency of Use of Cosmetic Ingredients. College Park, MD [Obtained under the Freedom of Information Act from CFSAN; requested as "Frequency of Use Data" 2023; received February 2, 2023].
- 17. Personal Care Products Council. 2025. Concentration of use by FDA Product Category; Acacia Senegal Gum and Acacia Senegal Gum Extract. [Unpublished data submitted by the Personal Care Products Council on March 31, 2025].
- 18. Sander I, Raulf-Heimsoth M, Wiemer K, Kespohl S, Brüning T, Merget R. Sensitization due to gum arabic (*Acacia senegal*): the cause of occupational allergic asthma or cross reaction to carbohydrates? *Int Arch Allergy Immunol.* 2006;141(1):51–56.

- 19. Doi Y, Ichihara T, Hagiwara A, et al. A ninety-day oral toxicity study of a new type of processed gum arabic, from Acacia tree (*Acacia senegal*) exudates, in F344 rats. *Food Chem Toxicol*. 2006;44(4):560–566.
- 20. Nasir O, Alqadri N, Elsayed S, et al. Comparative efficacy of Gum Arabic (*Acacia senegal*) and *Tribulus terrestris* on male fertility. *Saudi Pharm J*. 2020;28(12):1791–1796.
- 21. Avelino ALN, Silva NVRE, Oliveira GBD, et al. Antioxidant and antigenotoxic actions of gum arabic on the intestinal mucosa, liver and bone marrow of Swiss mice submitted to colorectal carcinogenesis. *Nutr Cancer*. 2022;74(3):956–964.
- 22. Nasir O, Wang K, Föller M, et al. Downregulation of angiogenin transcript levels and inhibition of colonic carcinoma by gum arabic (*Acacia senegal*). *Nutr Cancer*. 2010;62(6):802–810.
- 23. Al-Araimi A, Al Kindi IA, Bani Oraba A, et al. Gum arabic supplementation suppresses colonic fibrosis after acute colitis by reducing transforming growth factor β1expression. *J Med Food*. 2021;24(12):1255–1263.
- 24. Institue In VItro Sciences Inc. 2014Tissue Equivalent Assay EpiocularTM Cultures (1% Acacia Senegal Gum in a Mascara)2025 March 212025.
- 25. Institute for In Vitro Sciences Inc. 2023Topical Application Ocular Irritation Screening Assay using EpiOcularTM Human Cell Construct (Mascare with 3% Acacia Senegal Gum Extract). [Unpublished data submitted by the Personal Care Products Council on May 20, 2025].
- 26. Farcoderm. 2013. In Vitro Product Safety Study: In Vitro Evaluation of the Eye Irritation Potential of Cosmetic Products (Mascara Containing 2.9% Acacia Senegal Gum). [Unpublished data submitted by the Personal Care Products Council on July 22, 2025].
- 27. Anonymous. 2025. Summery Information: Eye Irritation Studies of Mascara Containing 6% Acacia Senegal Gum. Invitro Data of Bovine Corneal Opacity and Permeability Assay and Neutral Red Release Assay. [Unpublished data submitted by the Personal Care Products Council on June 23, 2025].
- 28. Farcoderm. 2013. Clinical Test Aimed at Evaluating the Tolerability and Safety of a Cosmetic Product used Around the Eyes (Mascara Containing 2.9% Acacia Senegal Gum). [Unpublished data submitted by the Personal Care Products Council on July 22, 2025].
- 29. Anonymous. 2025. Summary Information: Eye Irritation Studies of Mascara Containing 6% Acacia Senegal Gum. Product use Study. [Unpublished data submitted by the Personal Care Products Council on June 23, 2025].
- 30. Reliance Clinical Testing Services Inc. 2023Four Week Safety-in-use Test for Eye Area (Mascara with 3% Acacia Senegal Gum Extract). [Unpublished data submitted by the Personal Care Products Council on May 20, 2025].
- 31. Viinanen A, Salokannel M, Lammintausta K. Gum arabic as a cause of occupational allergy. *J Allergy (Cairo)*. 2011;2011:841508.
- 32. Tschannen MP, Glück U, Bircher AJ, Heijnen I, Pletscher C. Thaumatin and gum arabic allergy in chewing gum factory workers. *Am J Ind Med*. 2017;60(7):664–669.
- 33. Romita P, Bufano T, Antelmi A, Gelardi M, Foti C. Occupational allergic rhinitis and contact urticaria caused by Gum Arabic in a candy factory worker. *Contact Dermatitis*. 2018;78(6):427–428.