Orange Shellac

Handling/Processing

Identification of Petitioned Substance

Chemical Names: Orange shellac

Other Name:
Orange shellac, shellac gum confectioner's glaze, confectioner's resin, resinous glaze, candy glaze, pure food glaze and natural glaze, Lac resin

Trade Names:U-Beaut Orange Shellac, Grobet USA 12227 Shellac Flake, Kusumi Shellac Apple lustr, APL-BRITE, Decco Lustr 602,SSB Splendid, SSB Polisho

CAS Numbers:9000-59-3
Other Codes:
EINECS 232-549-9, EEC E904 52
ACX1009325-9

Summary of Petitioned Use

The use of the substance is in coating of fruits (citrus, pome, and stone fruit) and vegetables (cucumbers, bell peppers, eggplant, and potatoes). It may also be used in the pharmaceutical and confectionary industry (lozenges, capsules, tablets) confectionary glazes (chocolates, coffee beans, candy). Shellac dye is used as a food color.

Characterization of Petitioned Substance

Composition of the Substance:
Orange shellac is a resinous complex containing wax, dye and odoriferous components. The orange shellac is a polyester type of material, comprised of long chain and sesquiterpenic acids (Perez-Gago, et al. 2003).

Table 1. Composition of Orange Shellac (Bose and Sankaranarayan 1963)

Content	Percentage
Lac resin	70-80 %
Coloring pigments	4-8 %
Lac wax	6-7 %
Inorganic salts, sugar, and odor substance	15-20 %

The polyester complex is comprised of straight-chain fatty acids (9, 10, 16 trihydroxyhexadecanoic acid/aleuritic acid) and sesquiterpenic (jalaric) acid. Aleuritic acid is the main component among aliphatic acids. Other acids which have been isolated are butolic, shellolic, epishellolic, laksholic, epilaccishollolic and epilaccilaksholic acids (Bose and Sankaranarayan 1963).

Table 2. Composition of Bleached Orange Shellac (Mary Ann Liebert Publication 1986)

Content	Percentage
Acid value	73-89 %
Moisture	3-6%
Lac wax	4 - 5.5 %

Source or Origin of the Substance

Orange shellac or "shellac" as it is commonly known is the purified product of the natural resin lac which is the hardened secretion of the small, parasitic insect *Kerria lacca*, popularly known as the lac insect. Swarms of the insects feed on certain host trees. Their whole life cycle spans six months and is devoted to eating, propagating and creating shellac as a protective cocoon for their larvae. During certain seasons of the year, these tiny red insects swarm in such great numbers that the trees at times take on a red or pinkish color. When settled on the twigs and branches, they project a stinger-like proboscis to penetrate the bark. Sucking the sap, they begin absorbing it until they die. While they eat they propagate, with each female producing about one thousand eggs before dying.

In the body of the lac insect the digested tree sap undergoes a chemical transformation and is eventually secreted through pores. On contact with the air, it forms a hard shell-like covering over the entire swarm. In time this covering becomes a composite crust for the twig and insects. Only about five percent of the insects amassed on the trees are males. The female is the main shellac producer. The young nymphs leave the shellac covering and migrate to new twigs (Bose and Sankaranarayan 1963) shellac is the only known commercial resin of animal origin. Lac has been known in India and China since ancient times. Its use can be traced back to recordings from India from more than 2000 years ago. However, despite this wide distribution, the main production of shellac takes place in South-eastern Asia especially India, Thailand and Myanmar. Common lac host trees in India are Dhak (*Butea monosperma*), Ber (*Ziziphus mauritiana*), and Kusum (*Schleichera oleosa*), which is reported to give the best quality and yield. In Thailand, the most common host trees are Rain tree (*Samanea saman*) and Pigeon pea (*Cajanus cajan*). In China, the common host trees include Pigeon pea (*Cajanus cajan*) and Hibiscus species (Farag 2010).

Properties of the Substance:

Physical Properties:

Shellac is a hard, tough, amorphous and brittle resinous solid. It is practically odorless in the cold, but evolves a characteristic smell on heating or melting. Superior grades are light yellow in color, while the inferior grades range from deep orange brown to almost dark red.

Table 3. Physical properties of Orange Shellac (Bose and Sankaranarayan 1963)

Property	
Color	Brownish/Reddish
Odor	Resin like
Specific Gravity	1.035 to 1.214
Specific heat	1.513 to 1.529
Thermal conductivity	2.5mw/cm/°C
Flow/fluidity	50
Melt-viscosity	2250 PaS (Viscosity in Poise)
Molecular weight	1006
Softening point	65°Cto 70°C
Melting point	75°Cto 80°C
Solubility	In alkaline solutions such as ammonia, sodium borate, sodium carbonate, and sodium hydroxide; in organic solvents such as ethyl alcohol, n-butyl alcohol, acetone, butyric acid, ethyl acetate (85%), lactic acid and acetic acid.

Chemical Properties:

Shellac is a natural bio-adhesive polymer and is chemically similar to synthetic polymers. Shellac is soluble in alkaline solutions such as ammonia, sodium borate, sodium carbonate, and sodium hydroxide, and also in various organic solvents. It dissolves well in blends containing ethanol or methanol. Shellac is water insoluble.

Upon mild hydrolysis, shellac gives a complex mix of aliphatic and alicyclic hydroxy acids and their polymers that vary in exact composition depending upon the source of the shellac and the season of collection. The major component of the aliphatic component is aleuritic acid, whereas the main alicyclic component is shellolic acid. Shellac is UV-resistant, and does not darken as it ages (The Gale Group 2013). Shellac is acidic in character. Chemical properties of orange shellac are as below:

Table 4. Chemical properties of Orange shellac (Bose and Sankaranarayan 1963)

Properties	Value
Acid value	70
Saponification value	230
Hydroxyl groups	5
Hydroxyl number	260
Iodine value	18
Carboxyl value	18
Average molecular weight	1000
Normal wax content	5 %

Shellac is a natural material with a complex mixture of esters and polyesters of polyhydroxy acids. The first systematic analysis of its composition was performed by Tschirch et al. in 1899 after fractionation of the material in different solvents. Variations of this method have been used up to the present for separation of the shellac components. The molecular structure of the ingredients was analyzed and revised several times until the structure of the main components aleuritic acid and shellolic acid was clarified. It was found that depending on the shellac type, aleuritic acid and homologues of shellolic acid make about 70 percent of the total shellac composition. In later studies, butolic acid and other sesquiterpenic acids related to shellolic acid were identified as further components of the lac resin. Besides the individual acids, several esters have been identified along with the position of their linkages. These findings have been confirmed and further specified by modern analytical methods such as liquid and gas chromatography or combined pyrolysis and mass spectrometry (Farag 2010).

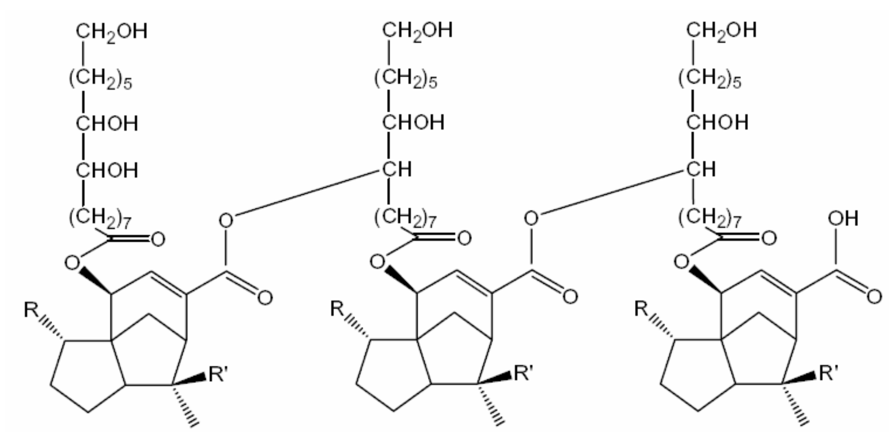

Fig. 1. Chemical structure of shellac (Sontaya Limmatvapirata 2004)

Specific Uses of the Substance:
FDA status allows its use as an additive in food products, which is the most common application of shellac.

Fruit Coatings – Shellac is used to coat fruits to make them shinier, reduce water loss and retain firmness. Waxes prevent moisture loss during fruit storage. Although natural waxes on fruits are effective in preventing water loss, the application of commercial wax can further decrease water loss during prolonged storage (Kolattukudy 1984)**.**Shellac is recognized as one of the shiniest coatings. It is used to coat apples and citrus to improve the appearance by adding gloss and to prevent water loss that leads to shriveling and subsequent loss of marketability (Musa, et al. 2013).

It has been reported that shellac coatings prevent early penicillum-induced postharvest decay by supporting populations of bacterial and yeast antagonists (McGuire and Hagenmaier 2001).

Confectionery **-** Shellac is used to provide protective candy coatings or glazes on candies like Reese's Pieces, because of its unique ability to provide a high gloss in relatively thin coatings (like a French polish). It is approved by the FDA as a food safe coating.

Pharmaceutical **-** Shellac is used to coat enteric pills so that they do not dissolve in the stomach, but in the lower intestine, which alleviates upset stomachs. It's also used as a coating on pills to "time release" medication.

Other uses of shellac **-** Wood treatment (primers, high gloss and mat polishes); electrics (insulators); printing inks, inks and china inks; cosmetics (binder for mascara, shampoo, film former for hairspray, micro encapsulation of fragrances); dental; hat manufacturing (for stiffening); conditioning for wooden floors; leather finishes; pyrotechnics; coating of seeds; micro encapsulation of dyestuffs, and as an abrasives binder for grinding wheels also known as 'gum lac', shellac also finds its way into household products such as sealing wax, adhesives, polish and varnish. It is also used in flexographic printing inks, leather finishing, and hat proofing and packaging industries.

Approved Legal Uses of the Substance:

- FDA 21 CFR 175.105 Shellac as a food additive for the use as adhesive for food packaging
- FDA 21 CFR 175.300 Shellac as a component for coating in contact with foods
- FDA 21 CFR 73. Diluents in color additive mixtures for food use exempt from certification
- FDA 21 CFR 175.380 Xylene-formaldehyde resins condensed with 4,4′-isopropylidenediphenol-epichlorohydrin epoxy resins.
- USDA organic regulations: Section 205.606(s); allowed as a nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Action of the Substance:

Coating/waxing prevents moisture loss, enhances firmness retention and slows down the fruit/vegetable respiration rate increasing appearance, shine and shelf life. It reduces moisture and mold attack.

The shellac coatings intensify the gloss, seal the crown and give a glossy barrier against high humidity and high temperature. They have low permeability to gases and moderate permeability to water vapor (Baldwin, Hagenmaier and Jinhe 1995). Shellac based formulations increase the resistance of the fruit skin towards gaseous diffusion, thereby reducing the internal oxygen concentration. Increase in carbon dioxide concentration retards respiration rate and retards ripening changes such as yellowing and de-formation. Similarly, such coatings reduce production of ethylene, which normally triggers off further maturation and ripening (Sarkar and Kumar 2003)**.**

Combinations of the Substance:

As a component of a fruit coating, orange shellac is almost always processed with a number of substances like isopropyl alcohol, morpholine, oleic acid, candelilla wax, fatty acid soaps and fast drying solvents (Saftner 1999). Other common combinations include wood rosins, paraffin wax, petroleum wax, carnauba wax, sugar cane wax, polyethylene emulsions, castor oil, triethanolamine, ammonia, sodium o-phenyl phenate, stearic acid, alkyl naphthalene sulfonates, sodium hydroxide, bentonite, borax, potassium hydroxide, glycerol, palmitic acid, luric acid, and stearic acid (Lexportex 1983).

Chemicals such as fungicides, growth regulators and preservatives can also be incorporated especially for reducing microbial spoilage and for sprout inhibition (Verma and Joshi 2000).

Plasticizers like castor oil, vegetable oils (corn, soy, etc), acetylated monoglycerides, fatty acids, etc. that are not soluble in water can be used in formulating shellac products. Plasticizers are additives that increase the plasticity or fluidity of material. Coloring agents such as dyes, titanium dioxide, iron oxide, natural colors and other materials such as talc, calcium carbonate and alumina may be used (Signorino 2003).

Several composite and bilayer films have been investigated with the goal of combining the desirable properties of different material to improve permeability characteristics, gloss, strength, flexibility, nutritional value, and general performance or coating formulations. Plasticizers have been incorporated into edible coatings as a processing aid to facilitate coating application and to increase merchantability (Thirupathi 2006).

Although many substances not permitted on organic food are used in combination with shellac in fruit coatings, there are also commercially available shellac-based fruit coating products in which the shellac is combined only with substances permitted by organic regulations (OMRI 2013).

Status

Historic Use:
Orange shellac was reviewed and voted for listing on the National List by the NOSB in 2002 under the general term "Shellac, Orange – Unbleached." It is a nonorganically produced agricultural product allowed as an ingredient in or on processed products labeled as "organic" and is currently listed as such at section 205.606(s). It is used primarily as a fruit coating along with wood rosin and carnauba wax. Historical use in organic food processing appears to be primarily limited to its use as a component of fruit waxes.

Organic Foods Production Act, USDA Final Rule:
Orange shellac is not mentioned in OFPA. It is mentioned in the final rule as "Shellac, Orange – Unbleached (CAS # 9000-59-3), 7 CFR 205.606 –Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

International

Canada - Canadian General Standards Board Permitted Substances List–
Orange shellac is currently not listed in the Canadian General Standards Board Permitted Substances List. Therefore, it is not permitted for use in organic processed foods in Canada.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (GL 32-1999)-
Orange shellac is currently not listed in CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

Orange shellac is currently not listed in European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008. Therefore, it is not permitted for use in organic processed foods.

Japan Agricultural Standard (JAS) for Organic Production —
Orange shellac is currently not listed in Japan Agricultural Standard (JAS) for Organic Production. Therefore, it is not permitted for use in organic processed foods.

International Federation of Organic Agriculture Movements (IFOAM) –
Orange shellac is currently not listed in International Federation of Organic Agriculture Movements (IFOAM) standards for organic production. Therefore, it is not permitted for use in organic processed foods.

Evaluation Questions for Substances to be used in Organic Handling

Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

Orange shellac is collected from a natural source, i.e., lac insect *Kerria lacca* (synonym *Laccifer Lacca*), a scale insect that feeds on host trees. Several species of trees are host to the lac insect, including *Dalbergiu* species and *Flemingia* species, which are shrubs introduced because of the ease of harvesting the insects from them. Even though many of these lac hosts exist, only few are used for large scale cultivation. The host trees are intercropped with upland rice or corn in Simao, Lingchang, and Baoshan (China) prefectures (Huijun and Padoch 1995). The major hosts in India are the Palas tree (*Butea monosperma*), the Ber tree (*Zizyphus mauritiana*) and the Kusum tree (*Schleichera oleosa*). In Thailand, the major host is the Rain tree (*Samanea saman*) (Farag 2010).

Young larvae of lac insects are red and measure about half a millimeter in length and half as much in width. After emergence, they settle down on the lac host and attach themselves to the host by piercing its bark. They suck the sap of the host and start secreting lac. Under this coating the larvae grow while they continue the secretion of lac from the inside. After eight to fourteen weeks, the male insect emerges out of its lac cover, fertilizes the female and dies soon after. The female continues growing and increases lac secretion until the egg laying period (Bose and Sankaranarayan 1963).

The crop is collected by cutting down the lac-bearing twigs and scraping off the so-called sticklac. The harvested sticklac is cleaned from wood and insect residues to produce intermediate seedlac. After refining seedlac, shellac is produced. See Figure 2.

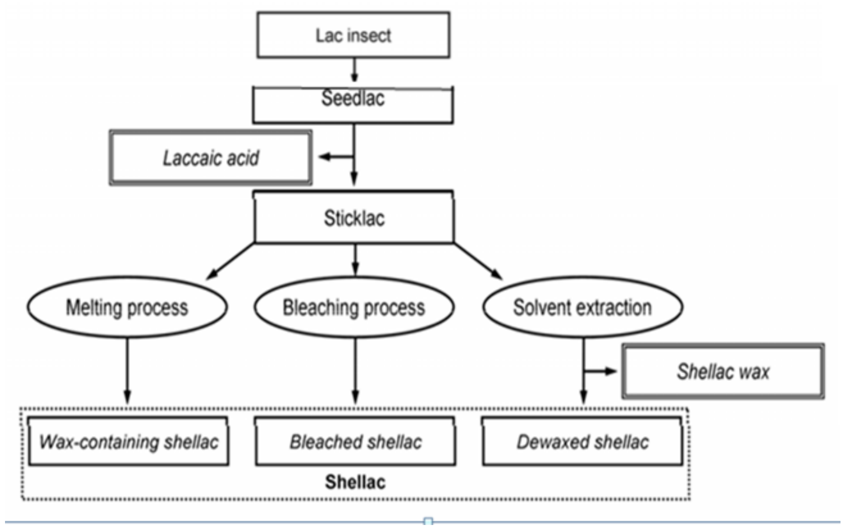

Fig. 2. Flow chart of the refining process of orange shellac (Farag 2010)

Refining the Crusty Resin

Workers cut millions of encrusted branches, called sticklac, for transportation to refineries. At refining centers, sticklac is scraped to remove the secretions from the twigs. Sticklac and the consequent product called grainlac is ground with rotating millstones. The resulting ground material is quite impure, containing resin, insect remains, twigs, leaves, etc. Sodium carbonate may be added in order to soften and separate wood pieces, and to remove lac dye and insect remnants from the resin-wax mixture. Differing amounts of water, time, and sodium carbonate are used to obtain various end results of color. The mixture is forced through a screen, removing the largest of the impurities. Most of the lac dye is washed out of the seedlac at this stage (Turing and von Fraunhofer 2006).

The sifted resin mixture is put into large tanks and stomped by a worker to crush granules and force the red dye from the lac seeds and to free the insect remains from the resin. Dye water, scum, and other impurities are then washed away in several rinses. The mixture is spread out on a concrete floor to dry and is commonly called seedlac because it resembles seed. Seedlac is graded on the basis of color, and the amount of insoluble impurities when dissolved in hot alcohol. Many of the various grades of seedlac are “polished” with oxalic acid, in order to lighten the color, and make the product shine more brightly. This is done by dissolving oxalic acid crystals in water, and mixing this solution into seed lac. The seed lac with the oxalic acid is then again spread out to dry in the sun. The oxalic acid is not removed or washed out of the product (Derry 2012).

Seedlac is the raw material from which orange shellac is produced. Orange shellac may be made from seedlac by hand or by modern mechanical equipment. Nearly all orange shellac consumed by the U.S. is refined with the help of machinery, using a heat-or solvent-based process.

Heat Process

For the heat process, the heat source is a furnace/oven built of local clay, and heated with coal. The filter in this process is a densely woven cloth bag, filled with seedlac. The seedlac inside the bag starts melting at around 75-80 degrees Celsius. As the seedlac heats and melts, it seeps through the bag, the canvas acting as a filter. The molten lac comes through, while the impurities such as wood and insect remains stay inside the tightly twisted bag. A stone slab in front of the fire is kept wet, so it can help cool the molten lac without the resin sticking to the surface. A worker then stretches the warm mass with his hand and feet into sheets of desired thickness. These sheets are left to cool and become brittle, after which they are broken into flakes, and later packaged as orange shellac (Turing and von Fraunhofer 2006).

In recent times there has been some improvement in processing where seedlac is melted onto steam-heated grids. The molten lac is forced by hydraulic pressure through a sieve or screen, either of cloth or fine mesh. The filtered shellac is collected and transferred to a steam-heated kettle, which then drops the molten liquid onto rollers. The liquid is squeezed through the rollers and forced into large, thin sheets of shellac. When dry, this orange shellac sheet is broken into flakes (Turing and von Fraunhofer 2006).

Solvent Process

In this process, the seedlac and solvent, usually ethyl alcohol, are mixed in a dissolving tank, refluxed for about an hour and then filtered to remove impurities. The filtered resin is then passed through a series of evaporators, until no alcohol remains, and the molten lac is stretched and rolled out into sheets, left to cool, and later broken into flakes or buttons. This liquid is then dropped onto rollers, which force it into sheets. The sheets are then are dried and flaked apart. The solvent process can either produce wax-containing, dewaxed or dewaxed-decolorized shellac (Turing and von Fraunhofer 2006). Dewaxed forms are produced by additional filtration presses prior to flaking. Decolorized forms are produced by the solvent method; the coloring matter, erythrolaccin is removed by using activated carbon filters. De-colorization by this method is carried out on dewaxed product only (Martin 1982) .

Bleached shellac

Bleaching begins with dissolving seedlac, which is alkali-soluble, in an aqueous solution of sodium carbonate. The solution is then passed through a fine screen to remove insoluble lac, dirt, twigs, etc. The resin is then bleached with a dilute solution of sodium hypochlorite to the desired color. The orange shellac is then precipitated from the solution by the addition of dilute sulfuric acid, filtered, and washed with water. It is dried in vacuum driers and ground into a white powder (Turing and von Fraunhofer 2006).

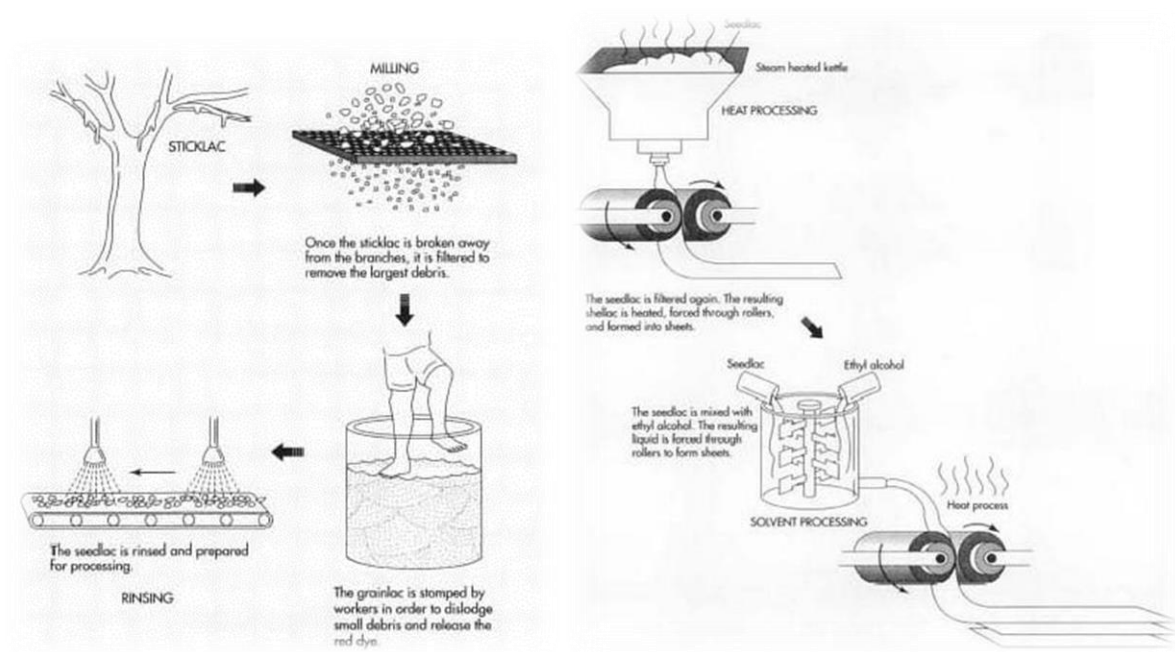

Fig. 3 Refining Process of Crusty Resin (Turing and von Fraunhofer 2006)

Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.

Orange shellac is produced naturally by the lac insect. However, during processing and formulation steps, it may get subjected to chemical changes. There are minor processing differences followed by various manufacturers.

During refining of the crusty resin from sticklac, sodium carbonate may be added, and there may be traces of it remaining in the product. Oxalic acid used in order to lighten the color and make the product shine more brightly may also create chemical changes. The solvent extraction process makes use of ethyl alcohol; however, this alcohol is completely removed by evaporation. No study on alteration of chemical structure of the shellac is reported. De-colorization uses activated carbon and/or sodium hypochlorite. The former is an adsorbent that does not affect the resin's chemical composition; however, treatment with the latter may result in chemical changes.

Evaluation Question #3: If the substance is a synthetic substance, provide a list of non-synthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

Orange shellac-unbleached, is currently classified as agricultural according to section 205.606(s). However, it cannot be used in pure, natural form. The crude from is unusable and it has to go through basic processing as described above before it can be used.

Evaluation Question #4: Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.

The WHO/FAO Joint Expert Committee on Food Additives (UN FAO/WHO Joint Evaluation Committee on Food Additives 1993) reviewed the effects of orange shellac on health, and the committee concluded that there were no toxicological concerns when used as coating, glazing, or surface finish agents applied externally to food. An orange shellac trade group claims that shellac is listed by FDA as GRAS (Sankarnarayanan 1989); however, it is not listed as such by the FDA in the regulations or the GRAS Notice Inventory.

Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600 (b) (4)).

Chemical food preservatives are defined under FDA regulations at 21 CFR 101.22(a)(5) as "any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties" (FDA 2014).

The typical use of the substance is in coating of fruits and vegetables. Coating/waxing prevents moisture loss, enhances firmness retention and slows down the fruit/vegetable respiration rate, improving appearance, shine and shelf life. It reduces moisture and mold attack.

Applying wax formulations to fruits appears to be mainly to improve attractiveness, although some improvement in storage quality has also been noted (Thirupathi 2006). As it is a natural, non-toxic resin, shellac is used in the food industry as a coating for processed foods, fruits and candies, as well as for pharmaceuticals (Derry 2012).Fruit coating and film treatments function as barriers to water vapor, gases, volatile compounds and ethylene transmission. Edible coatings are the method of extending post- harvest shelf life. Edible coatings provide a semi-permeable barrier against oxygen, carbon dioxide, moisture and solute movement, thereby reducing respiration, water loss and oxidation reaction rates (Baldwin, Hagenmaier and Jinhe 1995).

<u>Evaluation Question #6:</u> Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).

Orange shellac fruit coatings are used for better retention of fresh weight and flesh firmness, by lowering total volatile levels during storage, and to reduce respiration and ethylene production rates (Saftner 1999).Most freshly harvested fruits have their own waxy coating that protects them from shriveling and weight loss. Fruits are washed at the fruit packing sheds to remove dust and residues. This washing removes about half of the original fruit wax which is then replaced by a natural coating like orange shellac. Waxing prevents moisture loss, enhances firmness retention and slows down the fruit respiration rate. It can decrease fruit peel permeability, modify the internal atmosphere, reduce water loss and depress respiration rate (Musa, et al. 2013).

Currently, the commercial use of fruit coatings is primarily as applications for cosmetic effect, e.g., increased gloss, and reduced transpiration losses post storage. Shellac coatings also retain flesh firmness (texture) better (Saftner 1999).Synthetic or natural resins may be added to the wax emulsions to give more gloss to the treated produce (Thirupathi 2006). Coatings also prevent spoilage by serving as a barrier to water vapor. In 'Golden Delicious' apples, shellac- and wax-based coatings delayed ripening as indicated by better retention of fresh weight and flesh firmness, by lowered total volatile levels during storage, and the reduced respiration and ethylene production rates that were observed upon transferring the fruit to 20°C (Saftner 1999).

<u>Evaluation Question #7</u>*:* Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR § 205.600 (b) (3)).

The literature reviewed in this report does not specify that orange shellac based fruit waxes have any particular effect on nutritional quality. Apart from increasing shelf life of the coated product, orange shellac formulations are reported to aid in conservation of essential oils. They also increase the resistance of fruit skins towards gaseous diffusion, thereby reducing the internal oxygen concentration. Increase in carbon dioxide concentration slows respiration rate and retards ripening changes such as yellowing and deformation. Similarly, such coatings reduce production of ethylene, which normally triggers further ripening (Sarkar and Kumar 2003).

However, a potential disadvantage of fruit coatings and films is that the fruit may become anaerobic with the associated development of off flavors and/or off odors (Saftner 1999).

<u>Evaluation Question #8:</u> List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance(7 CFR § 205.600 (b)(5)).

The Joint FAO/WHO Expert Committee on Food Additives comments that present uses (as a coating, glazing, and surface-finishing agent externally applied to food) are not of toxicological concern (UN FAO/WHO Joint Evaluation Committee on Food Additives 1993). No evidence of contamination through heavy metals is reported.

<u>Evaluation Question #9:</u> Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

The actual production and processing of orange shellac does not seem to have major adverse environmental effects. Solvents and chemicals used during extraction and processing may cause some negative environmental effects during recovery and disposal. However, hygienic disposal of lac factory effluents may be a subject of concern.

Wash water originating from processing units contain water soluble dye, fragments from insect bodies, proteinacious matter, vegetable glue and some sugars. These effluents collect in a pit outside factories and putrefy, generating an offensive smell. This may be a potential environmental hazard for which further studies are required. During washing of sticklac to seedlac, the effluents of lac factories are allowed to flow and collect in reservoirs. This accumulated water is treated with acid, precipitating all solid matter called lac-mud. Lac-mud is also a source of lac dye and lac wax (Baboo and Goswammi 2010).

<u>Evaluation Question #10:</u> Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

There have been no reports showing adverse effects on human health due to orange shellac. Some individuals may show allergic symptoms and some vegetarians may consider it as animal product not suitable for their consumption.

The acute oral toxicity of four types of food-grade orange shellac was determined in rats. No deaths were reported. Long-term carcinogenicity studies have not yet been reported. Reproduction/teratogenicity studies in rats did not show negative results. Food grade regular bleached shellac was evaluated for mutagenicity in a series of *in vitro* microbial assays. No adverse effects were reported. No information on human oral dosing was available. Allergies, particularly bronchial asthma and allergic skin reactions, were reportedly caused by exposure to chemical compounds in the orange shellac industries through reports of patients exposed to the compounds as customers or workers in these industries. However, the respiratory allergies reported to be associated with inhalation of orange shellac may not be due to orange shellac but to other solvents (Mary Ann Liebert Publication 1986).

Orange shellac has an acceptable present use (as a coating, glazing, and surface-finishing agent externally applied to food) that is “not of toxicological concern” established at the 39th Joint Experts Committee for Food Additives (1992).

<u>Evaluation Question #11:</u> Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m)(6)).

Corn zein and starch are alternative materials for shellac that give high gloss. Zein is a protein of the prolamine group occurring in maize and used in fruit coating. Zein based coatings (14 to 20% zein) were developed for whole apple fruit as an alternative to shellac for high gloss fruit coating (Gennadios 2002). Zein was evaluated on tomatoes and resulted in modified internal atmosphere, color change, inhibition of weight loss and delayed softening. Carnauba wax has been used commercially to coat apples but has less gloss than shellac (Jinhe, Baldwin and Hagenmaier 2002).

For preventing the reduction of fruit weight, the primary function that citrus fruit waxes provide, the literature provides very little evidence of effective alternatives to waxes. Rather, studies have shown that altering the composition, concentration, and other factors of fruit waxes can positively or negatively affect loss of fruit weight (Dou, Ismail and Petracek 1999). Investigations on individual polyethylene (plastic) shrinkable wraps have demonstrated that water loss can be reduced without negatively influencing the exchange of respiratory gases or fruit flavor and nutritional value (Reuther, Calavan and Carman 1989). Purvis (1983) found that seal-packaging maintained the fresh appearance of citrus fruits at room termpature, but did not alter the rate at which internal acidity decreases. Thus, a problem for long-term storage of seal packaged fruit is the development of off flavors. The atmospheric storage conditions also influence water loss. The vapor pressure deficit of the atmosphere is changed by the temperature and the relative humidity of the ambient air. High temperature and low relative humidity cause rapid loss of water from the fruit; low temperature and high humidity, on the other hand, produce a low vapor pressure deficit and minimize water loss. Therefore, handlers can reduce water loss by monitoring and controlling the atmospheric conditions as much as possible during storage and transport. However, this practice should take into account the different varieties and their susceptibility to chilling injuries and other storage issues (Reuther, Calavan and Carman 1989).

Although the literature does not agree on how effective orange shellac fruit waxes are in preventing decay, they have been shown to prevent likely disease vectors from coming into contact with the fruit surface by forming a physical barrier. Some alternatives to using waxes as a prevention mechanism include the use of hot water sprays, and sodium carbonate and bicarbonate applications (Palou, et al. 2001). However, it should be noted that these applications were more effective in preventing decay in short-term storage and less so in long-term cold storage. Porat, et al. (2000) found that a hot water brushing treatment in organic citrus fruit reduced decay development by 45-55% in certain citrus cultivars, and the treatment at 56ºC did not cause surface damage, nor influence fruit weight loss or other quality factors. Further, they found that the hot water treatment smoothed the citrus fruits' natural epicuticular wax and thus covered and sealed stomata and cracks on the surface, which may have prevented pathogen invasion.

<u>Evaluation Question #12:</u> Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

There are primarily four different non-synthetic substances that may be used in place of orange shellac as a component of citrus fruit waxes: wood rosin, carnauba wax, beeswax and candelilla wax. Each has their own positives and negatives for various factors, including shine, permeability, cost, etc. Of these four, only wood rosin and carnauba wax are permitted as non-organic ingredients in fruit waxes used on organic fruit. Otherwise, organic beeswax and organic candelilla wax would be required for use on organic citrus fruits. See question 13 below for more complete information on beeswax.

A number of other non-synthetic and agricultural substances have been briefly studied as alternatives to or in combination with the four primary waxes, including corn zein, xanthan gum, grain sorghum wax, casein, soy protein, and chitosan. (Hagenmaier 1998; Krochta, Baldwin and Nisperos-Carriedo 1994).

It should be noted that nearly all the literature reviewed in this report suggests that all the alternative substances here are influenced by the quality of the emulsions and also the necessary presence of minor ingredients to facilitate and enhance certain characteristics. Therefore, the viability of any alternative substance should be taken into account along with the need for other components to enhance the performance of the primary wax substance.

Wood Rosin

Wood rosin is a complex organic mixture composed of rosin acids, oxidized and modified forms of these, and neutral and colored constituents associated with dark rosin. Wood rosin is used in organic processing and handling primarily as a fruit wax. FDA regulations at 21 CFR 172.210(b) (2) stipulates that wood rosin (grade K) may be used as "coatings applied to fresh citrus fruit for protection of the fruit". Modified versions (e.g. glycerol esters of wood rosin) of wood rosin are otherwise used as ingredients in beverages containing citrus oils but do not result in more than 100 ppm in the final beverage (21 CFR 172.735). No organic versions are available at this time (Merck 2013).

Carnauba wax

Carnauba wax is reported to have low oxygen and moisture permeability, though it is more permeable to O_2 and CO_2 than wood rosin and shellac (Hagenmaier and Shaw 1992). The gas barrier also impedes oxidation of oils which in turn reduces rancidification of fatty foods such as nuts. Maintaining internal oxygen levels of fruit with dilute concentration of carnauba wax coating can also maintain flavor (Hagenmaier and Shaw 1992;Hagenmaier and Baker 1994) found that oranges coated with carnauba wax based fruit coatings had less weight loss, lower internal CO_2, higher internal O_2, and better water resistance than those coated with wood rosin or shellac.Used as a fruit coating, carnauba wax acts as it does on the plant on which it originates: it reflects light giving the fruit a shiny appearance, reduces loss of moisture and mass, prevents fungal attack and postpones decay. Carnauba wax prevention of fungal attack in post-harvest fruit can also be attributed to antifungal properties beyond just creating a gas barrier. One study in which proteins were isolated from the various fractions of carnauba wax found antifungal enzymatic activity of the proteins. These enzymes, chitinase and β-1, 3-glucanases, can inhibit early growth of fungi and alter fungal hyphae (thread like filaments forming the mycelium of a fungus) morphology of fungi growing in the presence of the proteins (Cruz 2002). Carnauba wax is also available in organic forms, as opposed to wood rosin and orange shellac, and is formulated in products compliant for use as fruit waxes on organic foods (OMRI 2013). The 2012 list of certified USDA organic operations (National Organic Program 2012) lists seven operations in Germany, Brazil, and the U.S. that produce or handle organic carnauba wax. It should be noted however that the literature suggests that carnauba wax is often formulated with other waxes such as shellac, wood rosin, beeswax, and candelilla in order to produce the most advantageous characteristics (Dou, Ismail and Petracek 1999). Therefore, its use as an alternative to wood rosin primarily depends also on the availablility of other substances for further formulation in edible coatings.

Candelilla wax

Candelilla wax is obtained from the desert plant *Euphorbia antisyphilitica* and is extracted from the leaves with boiling water (Hagenmaier and Baker 1996). It is a hard wax that has been studied extensively as a component of fruit coatings, especially for citrus (Hagenmaier and Baker 1993) (Bosquez-Molina, Guerrero-Legarreta and Vernon-Carter 2003)found that coatings containing candilla wax provided an "attractive gloss" to the fruits, did not alter the chemical composition of limes, and had differing affects on color retention of the peel. For example, a mesquite gum-candelilla wax-mineral oil emulsion applied to the limes prevented the most weight loss and had the highest gloss, providing the fruit with a fresher appearance than candelilla wax alone. Candelilla wax is also used to improve the shelf life and quality of avocado by minimizing the changes in appearance, solids content, pH, and weight loss. Candelilla wax has the lowest permeability to water vapor of any lipids (Krochta, Baldwin and Nisperos-Carriedo 1994). However, it should be noted that the literature suggests that candelilla wax based fruit coatings are often formulated with other components such as carnuaba wax, wood rosin, orange shellac, beeswax, vegetable oil, ammonium, and morpholine (Krochta, Baldwin and Nisperos-Carriedo 1994) (Hagenmaier and Baker 1996). Thus, it should not be considered to be a complete replacement for wood rosin without the availability of other compliant components. There are currently no certified organic sources of candelilla wax (National Organic Program 2012).

Evaluation Information #13: Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b) (1)).

Of the alternatives discussed in Question 12 above, only carnauba wax and beeswax are commercially available in organic form (National Organic Program 2012). See Question 12 for more information about organic carnauba wax as an alternative to orange shellac.

Beeswax

Beeswax, also known as white wax, is secreted by honey bees for comb building. It is harvested by removing the honey and melting the wax with hot water, steam, or solar heating. It has been studied as a component of fruit waxes, although not as extensively as carnauba wax, orange shellac, and wood rosin (Krochta, Baldwin and Nisperos-Carriedo 1994). Hagenmaier (1998) found that beeswax emulsions must be made with other waxes and with 50% or more beeswax, the turbidity increased. Further, the beeswax formulations had very low gloss.However, beeswax is a very good barrier to water and has been found to have anti-browning effects on cut fruit (Perez-Gago, et al. 2003). However, Perez-Gago *et al.* (2003) did not find that the beeswax-whey protein emulsions affected weight loss in comparison to uncoated fruit. It has also been studied in combination with hydroxypropyl methylcellulose and various fatty acids (stearic acid, palmitic acid, and oleic acid) (Navarro-Tarazaga, et al. 2008). Researchers found that the coatings reduced weight and firmness loss while also preserving flavor quality in comparison to uncoated fruits. It should be noted that the literature suggests that beeswax based fruit coatings are often formulated with other components such as carnuaba wax, wood rosin, orange shellac, candelilla wax, vegetable oil, ammonium, and morpholine(Krochta, Baldwin and Nisperos-Carriedo 1994;Hagenmaier and Baker 1996). Thus, it should not be considered to be a complete replacement for orange shellac without the availability of other compliant components. There are currently 27 certified organic sources of beeswax (National Organic Program 2012).

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