Orange Shellac (unbleached)

Processing

Executive Summary

Shellac is derived from the hardened secretion of the lac insect, *Laccifer* (Tachardia) *lacca*. These are scale-like insects feeding on resiniferous trees and bushes cultivated in India and southeast Asia. The resin is secreted as a covering for the insect larvae. The lac is collected from host trees by cutting branches containing resinous insects, and grinding and further processing. Processing involves various steps, including melting,screening, and filtering, and can involve solvent extraction and de-colorising with activated charcoal.

The petitioned use is as a component of fruit and vegetable coatings, and as a coating agent for pharmaceuticals and confectionery products. The purpose cited is for forming a film on the coated product, improving cosmetic appearance, and providing moisture and atmospheric protection.

The NOSB considered shellac as part of a Technical Advisory Panel review for Waxes in September, 1999. The NOSB voted that shellac was synthetic, and recommended not to add it to the National List. The review at that time did not distinguish between bleached or unbleached forms of shellac. The TAP Reviewers for this TAP Review found that orange unbleached shellac is derived from natural sources, though one considered that the materials used in manufacturing rendered the substance synthetic and not compatible with organic standards. A second reviewer found that the uses of the material to extend shelf life, reduce water loss, and improve cosmetic appeal are not compatible with organic principles. The third reviewer found the material suitable for organic use, though expressed some concerns that consumers should be informed that products have shellac coatings applied, especially since there are some reports of allergenicity.

Note: The NOSB may want to investigate further if confectionery use is warranted, as this review does not examine this use in depth. The NOSB may also want to investigate possible options for labeling or otherwise identifying produce that contains coatings when sold at retail level.

Summary of TAP Reviewer Analysis[1]

95% organic

Synthetic / Non-Synthetic:	Allowed or Prohibited:	Suggested Annotation:
Synthetic – 1 Nonsynthetic – 2	Allow – 1, with annotation Prohibit – 2	For use as fruit coatings only.

Made with organic (70% or more organic ingredients)

Synthetic / Non-Synthetic:	Allowed or Prohibited:	Suggested Annotation:
Synthetic – 1 Nonsynthetic – 2	Allow – 3 2 – no annotation 1 – with annotation	Allowed only when labeled to indicate that a coating has been added.

[1] *This Technical Advisory Panel (TAP) review is based on the information available as of the date of this review. This review addresses the requirements of the Organic Foods Production Act to the best of the investigator's ability, and has been reviewed by experts on the TAP. The substance is evaluated against the criteria found in section 2119(m) of the OFPA [7 USC 6517(m)]. The information and advice presented to the NOSB is based on the technical evaluation against that criteria, and does not incorporate commercial availability, socio-economic impact, or other factors that the NOSB and the USDA may want to consider in making decisions.*

Identification

Chemical Name: Shellac

Other Names:
Lacca, lac. Unbleached shellac. Forms in commerce are orange shellac, orange shellac (wax-free), bleached shellac, bleached shellac (wax-free).

Trade Names:
Dewaxed Flake Shellac;
Formulations containing shellac: Shield-Brite, Fresh-Cote, PacRite, Citroshine, Appleshine, FMC-360HS

CAS Number: 9000-59-3

Other Codes:
EINECS 232-549-9, EEC E904
ACX1009325-9

Characterization

Composition:
A mixture of resins secreted by the lac insect. The resins are composed of a complex mixture of aliphatic and alicyclic hydroxy acids and their polyesters (Budavari, 1996; Martin, 1991). Components include aleuritic acid, shelloic acid, jalaric acid, and other compounds. A dye called laccaic acid is associated with the crude lac and removed by processing. The insect also secretes a thin white filmentous wax along with the lac resins, this may be removed also in processing.

Properties:
Shellac is a hard, tough, amorphous resin that has good water resistance and produces high lustrous finishes. It is soluble in alcohols, aqueous solutions of alkali, and organic acids and ketones, but insoluble in water (Martin, 1991; Budavari, 1989). Forms include brittle, yellowish, transparent sheets or crushed pieces, flakes or powder (Budavari, 1989).

How Made:
Shellac is derived from the hardened secretion of the lac insect, *Laccifer* (Tachardia) *lacca* Kerr (order Homoptera, family Coccidea), also known as *Kerria lacca* (Kerr). These are scale-like insects feeding on resiniferous trees and bushes cultivated in India, Burma, Thailand, Laos, Cambodia, and Vietnam. The resin is secreted as a covering for the insect larvae. The insects are collected from host trees by cutting branches containing young insects prior to a swarming stage. These branches are tied to new trees, where young larvae emerge and colonize young twigs, continually secreting resin.

The resulting product is called seed lac, and is further processed in a variety of methods to yield different products. These are classed as handmade, machine–made, and bleached shellacs. Although some is processed by hand, most commercial shellac is machine made using either a heat or solvent process. The heat process involves melting the seed lac and filtering under pressure through screens to produce standard grades of orange shellac (Martin, 1982; Class, 1991). The solvent process can either produce wax-containing, dewaxed, or dewaxed-decolorised shellac. This involves dissolving the seed lac in ethyl alcohol, heating, and filtering to remove impurities, then dehydrating and flaking. Dewaxed forms are produced by additional filtration presses prior to flaking. Decolorised forms are produced by treating with activated carbon after dewaxing (Martin, 1982). This is the process described by the petioner (Singhana, 2001).

Bleached shellacs are produced by dissolving seed lac in aqueous sodium carbonate at high temperature, centrifuging and filtering, and treatment with sodium hypochlorite. The solution is then acidified with sulfuric acid to preciptate the resin, which is further filtered ,washed, and dried. Wax-free or wax-containing grades may be produced, depending on additional filtration steps (Martin, 1982).

Specific Uses:
In food, shellac is used as a coating agent, color diluent, surface finishing agent, glazing/polishing agent, and used in confectionery, food supplement tablets, as well as chewing gum. Additional uses are as a component of adhesives for food contact, in packaging, inks, pharmaceutical coatings, cosmetics, lacquers, and varnishes for wood, floor polish, manufacture of buttons, stiffening of hats, and finishing of leather (Budavari, 1996; Ash, 1995; Martin, 1982).

Action:
Shellac is used as an ingredient in edible fruit coatings to limit water loss and prevent desiccation and weight loss, and to prevent entry of pathogens. Shellac coatings are fairly impermeable to oxygen and water and form a barrier on the fruit surface that reduces gas exchange. Reduction in oxygen levels will reduce the rate of respiration of fruits and vegetables and prolong shelf life by delaying the oxidative breakdown of the product. This also causes reduced production of ethylene, which normally triggers further maturation and ripening. Shellac waxes are also added to provide high-gloss finishes to fruit for cosmetic purposes (FDA, 2001; Hagenmaier, 2000; Kaplan, 1986).

Combinations:

Shellac is applied in combination with other ingredients when used in fruit and vegetable coatings. Many different formulations of coatings have been investigated and developed to provide different degrees of gas and water permeability. According to the petitioner, shellac content can range from 2-45%. Other ingredients that may be used include carnauba wax, wood resins, polyethylene emulsions, paraffin wax, petroleum wax, candelilla wax, oleic acid, lauric acid, stearic acid, palmitic acid, morpholine (as fungicide and plasticizer), ammonia, potassium hydroxide, oils, alcohol, and glycerol (FDA, 2001; Hagenmaier, 1994; Sankaranarayanan, 1989; McGuire, 1999).

Recent research on biocontrol of fruit rot has demonstrated efficacy of replacing fungicidal materials and ammonia with various ingredients (sucrose esters, potassium hydroxide, different surfactants) that support colonization of fruit surface by beneficial yeasts that are antagonist to blue mold fungi (McGuire, 1999).

Shellac used for confectionery glazing and pharmaceutical tablets may be dissolved in a solvent, usually ethanol but sometimes isopropyl alcohol is used. Shellac may also be dissolved in alkaline solutions such as sodium carbonate, borax, and ammonia, and in some instances morpholine or triethanolamine. Synthetic plasticisers, preservatives such as phenol, or the mixed methyl and propyl esters of p-hydroxybenzoic acid and anti-foam agents may also be added (Sankaranarayanan, 1989).

Status

Historic Use:
Lac has been used in India for several thousand years as a source of dye and decorative coatings. Records from the late 1500's Mogul ruler Akbar describe the use to decorate public buildings, as do writings of early Portuguese travelers (Martin, 1982). The Chinese applied molten waxes to oranges and lemons as early as the twelfth or thirteenth century. Ancient Greek and Roman writers were aware of it, and it became widely used in Europe for furniture finishes by the late fifteenth century (Class, 1991). In the US, waxes used on citrus initially were paraffin based in the 1930's, evolving to solvent based resins in the late 1940's. Carnauba waxes became popular in the late 1950's but were less popular due to lack of shine. Waxes containing shellac and various alkali soluble resins plus adjuvants were introduced in the early 1960's and have been widely used in citrus producing areas (Kaplan, 1986).

For organic use, natural waxes have been used in packing citrus fruits, particularly for export. Use in post-harvest handling of organic pome fruits and fruit vegetables such as cucumbers, summer squash, and bell peppers is a relatively recent phenomenon. Some certifiers have at various times had a restricted application only to "non-edible plant parts" with the implicit allowance for citrus but no other uses.

OFPA, USDA Final Rule: Shellac is not listed in OFPA or 7 CFR part 205. Unbleached shellac could be considered nonsynthetic, used in handling, and not organically produced under OFPA 6517(c)(1)(B)(iii).

Regulatory: EPA/NIEHS/Other Sources
Not listed in the NIEHS National Toxicology Program database.
As a non-active ingredient in pesticides, EPA lists shellac on List 3 - Inerts of unknown toxicity (EPA, 2001).

The petition and literature from a shellac trade group claim that shellac is listed by FDA as GRAS (Singhania, 2001; Sankaranarayanan, 1989), but review of the FDA database did not confirm this (EAFUS, 2002). A proposed notice of GRAS affirmed status was filed in 1989 (FDA, 1989), but GRAS status was not officially granted. The proposed notice states that FDA had issued a letters of opinion that the substance is GRAS for use in candy coatings, and that predated the 1958 Food Additives Act, which would give it "prior sanction" status. However, shellac is not listed in the CFR as either GRAS, prior approved GRAS, or in the newer database of recently affirmed GRAS substances (FDA, 2002).

Regulated uses include:

CFR listing	Use
21 CFR 73.1	Diluents in color additive mixtures for food use exempt from certification
21 CFR 101.4 (b)(22)	Food Labeling--. 101.4 Food; designation of ingredients.
21 CFR175.105	Adhesives.
21CFR 175.300	Resinous and polymeric coatings
21 CFR 175. 380	Xylene –formaldehyde resins condensed with 4, 4'-isoprpylidenedip. (allows material listed in 175.300)
21CFR175.390	Zinc-silicon dioxide matrix coatings. (allows material listed in 175.300)
27CFR 21.127	Alcohol, Tobacco Products And Firearms, Formulas For Denatured Alcohol And Rum—Subpart E--Specifications for Denaturants: Shellac (refined).

Waxes used on fresh produce are considered ingredients by FDA and are required to be labeled as follows:

> 21 CFR 101.4: (b) The name of an ingredient shall be a specific name and not a collective (generic) name, except that:
> (22) Wax and resin ingredients on fresh produce when such produce is held for retail sale, or when held for other than retail sale by packers or repackers shall be declared collectively by the phrase "coated with food-grade animal-based wax, to maintain freshness" or the phrase "coated with food-grade vegetable-, petroleum-, beeswax-, and/or shellac-based wax or resin, to maintain freshness" as appropriate. The terms "food-grade" and "to maintain freshness" are optional. The term lac-resin may be substituted for the term shellac.

Status Among U.S. Certifiers

The NOSB considered shellac as part of a Technical Advisory Panel review for waxes in September, 1999 (NOSB, 1999). The NOSB voted that shellac was synthetic, and recommended not to add it to the National List. The review at that time did not distinguish between bleached or unbleached forms of shellac. Subsequently many certifiers included shellac as a prohibited material on their generic lists, as did OMRI (OCIA 2001; CCOF 2000; OMRI 2001). Currently US certifiers have modified their standards to be compliant with the NOP National List, and since shellac is not included it is considered prohibited.

International

CODEX – not listed
EU 2092/91 – Not listed. The EU list only mentions carnauba and beeswax as releasing agents, not as food coatings.
IFOAM Basic Standards 2000 – not listed
Canada – not listed.
Japan –not listed

Section 2119 OFPA U.S.C. 6518(m)(1-7) Criteria

1. *The potential of the substance for detrimental chemical interactions with other materials used in organic farming systems.*
   The material is used in processing, and does not have chemical interaction with farming systems.
2. *The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment.*
   See question 2 below.
3. *The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.*
   See question 2 below
4. *The effects of the substance on human health.*
   See questions 3 and 5 below.
5. *The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock.*
   The material is used in processing, and does not have interactions with farming systems. It is a natural material collected in a cultivated agricultural setting, generating income in a well-established cooperative market for tropical farmers (Viswanath, 1994; Kabra, 1983).
6. *The alternatives to using the substance in terms of practices or other available materials.*
   See questions 1 and 7 below.
7. *Its compatibility with a system of sustainable agriculture.*
   See question 6 below.

Criteria From the February 10, 1999 NOSB Meeting

A PROCESSING AID OR ADJUVANT may be used if:

1. *It cannot be produced from a natural source and has no organic ingredients as substitutes.*
   The lac resin is collected from a natural source, as described under "How Made." The lac insects could be cultivated under organic management systems, however there appear to be no certified organic sources of production currently available. For some uses, organic beeswax could be a substitute, though this may not be commercially available in amounts needed. Other materials permitted on the National List (though not organic ingredients) that can be used in fruit coatings include carnauba wax, wood resins, glycerin, potassium hydroxide, and organic oils or fats. Water based whey protein isolate has potential to replace shellac or corn zein coatings for use in confectionery products (Trezza, 2000).

   Fruit can be packed and stored without the use of shellac. Storage life can be extended through careful handling practices. Management of product storage environments through temperature and humidity control, and modified or controlled atmosphere, can extend storage life and prevent or delay the spread of infection of produce with pathogens (FDA, 2001). Citrus fruit has a natural layer of wax on the fruit surface, which can accumulate a residue of dirt, dust

mold, spray residues, and sooty blotch (a blackish mold that grows in secretions deposited by aphids). This is usually washed off in the packing house using detergents or water and brushes. The washing removes the natural waxes and increases rind permeability (Kaplan, 1986). Stricter grading, culling infected fruit, careful handling of produce during harvest and post-harvest to avoid physical damage, leaving the cuticle intact, reduced contact with excess foreign material, or contact with spoiled product can also reduce the possibility of opportunistic infections. Fruit was once commonly wrapped in plain paper (Ayres, 1890). Planned management of product flow to satisfy shorter shelf life through multiple pickings and picking to order is another possibility. Biological control with antagonists such as Candida oleophila can also be part of an integrated system of post-harvest pathogen reduction (McGuire, 1999).

2. *Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6510 of the OFPA.*

Manufacture of unbleached orange shellac using alkaline washing, heat, and mechanical filtration and use of activated charcoal to remove color does not appear to present any environmental adverse affects. Solvent extraction using alcohol or other solvents may pose recovery problems, which may be avoided when aqueous solutions are used (Krause, 2001; Trezza, 2000).

Bleached shellac manufacturing employs several additional extraction and refining steps that involve the use of strong acids, alkaline extractants, and oxidizing agents. Production and disposal of these synthetics may cause negative environmental consequences similar to that caused by other extracted materials.

Limited information was available about the effect of the lac harvest on the environment, though summaries of reports and description by the petitioner about collection practices support the claim that trees used for this purpose are repeatedly pruned and lopped to harvest the lac bugs. In some areas, tree species may serve multipurposes as fuel wood, fodder, construction materials, and be intercropped with rice paddies (Viswanath, 1994).

3. *If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations.*

The WHO/ FAO Joint Expert Committee on Food Additives (JECFA, 1993) reviewed effects 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. No information was available on long term carcinogenicity studies, however. Reproductive, teratogencity (animal testing), and mutagencity (bacterial) studies on showed no toxicological effects for bleached shellac.

In humans, some allergies to shellac have been reported, including bronchial asthma and skin reactions from cosmetic products, though other solvents may also be a factor. The FDA federal register notice of 1989 reported the findings of the Select Committee on GRAS Substances. They found that while no adverse affects had been reported for food uses of shellac over a long history, there was a lack of biological data regarding effects on animals or humans, and concluded they had insufficient data to recommend GRAS status. The possible effect of unsuspected contact of various components of fruit and vegetable coatings on sensitive individuals is a problem, as it is difficult to trace the use of food coatings that lack retail labeling (Frompovich, 1985).

While shellac coatings have long been known to improve storage life for some fruits, it is also widely reported that the impermeable coatings such as shellac and wood resin combinations result in lower internal oxygen, higher internal carbon dioxide, and a subsequent buildup of ethanol under anaerobic conditions. This leads to off-flavor in citrus (Baldwin, 1995; Hagenmaier, 2000; Hagenmaier, 2002) and loss of volatile flavor components in apples as well as increased browning disorders in one variety of apple (Saftner, 1999a; Saftner, 1999b; Lau, 1998). Extremely low oxygen levels that result in anaerobic conditions can favor growth of some food pathogens, such as *Clostridium*. Complete elimination of spoilage organisms is not considered to be a good idea, in that spoilage prevents pathogens from becoming a food safety issue (FDA, 2001). Formulations containing 10-17% shellac were effective in killing larvae of Caribbean fruit fly in grapefruit (Hallman, 1994). Shellac formulations with an alkaline base also reduced populations of coliform bacteria on citrus (McGuire, 2001).

Research is very active in this area, and many different combinations and materials have been studied and proposed, many of which are not approved for organic handling. These include plasticizers such as polyethylene glycol, anti-microbials, and antioxidants (FDA, 2001). Different formulations of fruit coatings that have greater permeability have been proposed, including some that have less problems with flavor loss and those that encourage bio-control of pathogens (Hagenmaier, 2002; McGuire, 1999).

4. *Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.*

The primary purpose of shellac when used in fruit or vegetable coatings is to reduce shrinkage due to water loss, provide a barrier to free gas exchange in order to prolong shelf-life, and improve appearance by adding a shiny film. It is also used as a base to provide carriers for decay controlling fungicides, or more recently for biocontrol agents used to prevent decay (Kaplan, 1986; McGuire, 1999).

It does not replace nutrients or improve flavors, but may act to reduce flavor in fruit coating formulations that are high in shellac (see above). Prevention of fruit senescence and decay will preserve nutrients and freshness in crops handled in ways that reduce the natural waxy coating (Kaplan, 1986).

As a coating it is used also for supplements and vitamins as a moisture barrier and is one of the few excipients allowed for this use (Krause, 2001).

5. *Is Generally Recognized As Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP), and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.*

As noted under the regulatory summary, shellac does not have GRAS status, though some uses may be considered approved by prior sanction. The Food Chemicals Codex 4th Edition does not provide specific criteria for unbleached shellac, and the Select Committee on GRAS noted in 1989 that there is a need to develop specifications for orange shellac, and that it planned to work with the Committee on Food Chemicals Codex to develop them. Until that time, the Select Committee proposed that orange shellac would be acceptable, provided it "is of appropriate food grade purity in accordance with 21 CFR 184.1(b) and 170.30(h)(1)."

Food Chemical Codex requirements for Shellac, Bleached:
Acid Value: Between 73 and 89
Heavy metals (as Pb): Not more than 10 ppm
Loss on drying: Not more than 6%
Rosin: Passes test
Wax: Not more than 5.5%

Shellac, Bleached, Unwaxed
Acid Value: Between 75 and 91
Heavy metals (as Pb): Not more than 10 ppm
Loss on drying: Not more than 6%
Rosin: Passes test
Wax: Not more than 0.2%

6. *Its use is compatible with the principles of organic handling.*

The NOSB principles of organic handling state:
"Organic processors and handlers implement organic good manufacturing and handling practices in order to maintain the integrity and quality of organic products through all stages of processing, handling, transport, and storage; Organic processors and handlers use practices that minimize environmental degradation and consumption of non-renewable resources. Efforts are made to reduce packaging; use recycled materials; use cultural and biological pest management strategies; and minimize solid, liquid, and airborne emissions" (NOSB, 2001).

One could consider that if suitable fruit coatings can be developed using natural materials, it promotes quality and integrity of organic products through all stages of transport and storage. Shellac is a renewable resource that provides income to producers in developing countries and may encourage diversified agroforestry uses. Organic fruit often requires washing to appear attractive in the market place due to less use of fungicides to control sooty blotch. Long distance transport of semi tropical fruit, such as citrus, or apples destined for other continents may be improved if suitable fruit coatings acceptable to consumers can be utilized.

On the other hand, applied fruit coatings might not be needed if the natural cuticle of wax found on fruit was maintained rather than scrubbed off during fruit cleaning at the packing shed. Shellac is a non-food materials that is applied to food products in order to replace natural oils or waxes removed from fresh produce, or to otherwise preserve produce in its harvested state for a longer than natural period of time. In some cases it is quite possible that these parts of the fruit are also eaten (apple skin, citrus peel used in baked goods.) As such, it is safer to consider waxes as an ingredient. There is currently no mechanism in the marketplace for consumers to know with certainty whether the product they buy is treated with wax, despite the fact that produce must be labeled on its case as to any treatments. Were retailers of organic goods required, by certification or other regulations, to clearly indicate when fresh produce has been treated with waxes, these materials might seem more acceptable for use on certified organic produce.

7. *There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.* Alternatives are described in processing criteria number 1. Research into appropriate formulations appears to be very specifically targeted to develop optimal levels to produce desired effects on gas permeability. Over use of the shellac component in a fruit coating can lead to flavor and quality problems, so it is more likely that shellac would be used as one ingredient in a formulated wax coating.

TAP Reviewer Discussion

Reviewer 1 *[Ph.D. food science and nutrition, minor in biochemistry. Organic processing consultant, organic inspector, nutrition researcher. Western US]*

Comments on Database

I find the database (Characterization and Status) to be reasonably complete and fairly accurate.
The technical information and research articles provided by OMRI were very comprehensive, as I could not find any additional references after conducting my usual computer literature search.

Also, I would request the petitioner, RENSHELL, provide more detailed explanation of manufacturing methods to assist in the evaluation of organic handling compatibility.

NOSB Processing Criteria Evaluation

1. *It cannot be produced from a natural source and has no organic ingredients as substitutes.*
   I agree with the criteria evaluation.

2. *Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA.*
   I agree with the criteria evaluation.

3. *If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations.*
   The criteria evaluation needs to be corrected or amended as follows:
   There is no data from the literature showing any adverse effects of the use of beeswax on the nutritional quality of fresh fruits or vegetables.

4. *Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.*
   The criteria evaluation needs to be corrected or amended as follows:
   The primary purpose of using protective coatings is to reduce weight loss of products through transpiration mechanisms of water vapor during the storage and transportation of fresh agricultural commodities.

5. *Is Generally Recognized As Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP), and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.*
   The criteria evaluation needs to be corrected or amended as follows:
   According to the literature and information provided in the RENSHELL petition to the NOSB for the de-waxed flake shellac, the major component is aleuritic acid, which is 9,10,16-trihydroxy palmitic acid, a hydroxylated form of naturally occurring palmitic acid…. According to 7CFR part 205.605 both non-synthetic waxes and carnauba wax are allowed as ingredients labeled as organic.

6. *Its use is compatible with the principles of organic handling*
   The criteria evaluation needs to be corrected or amended as follows:
   According to the RENSHELL petition documented on Annex 1, the preparation of the product from the Sticklac to the Seedlac phase appears to be compatible with organic process operations, provided adequate pesticide residue analysis is conducted. The purification of Seedlac to the Dewaxed Flake Shellac step is problematic. The ethanol used does not state if it is denatured (usually with another alcohol) or non-denatured as 100% ethanol and food grade, which would significantly increase its cost due to BATF federal taxes.

   Additionally the question of ethanol production from fermentation needs further clarification as to the GMO status of the yeast and/or enzyme systems. Clarification of the product is conducted by activated charcoal, which is not on the National List. Therefore, the chemical evidence indicates that shellac is a synthetic final product as long as it is manufactured according to the process as described in Annex 1. However, if organic ethanol were to be used for

purification with the Seedlac not subjected to final de-colorization, then a strong argument can be made for its compatibility with organic handling operations.

7. *There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process. The criteria evaluation needs to be corrected or amended as follows:*
Proposed methods to produce de-waxed flake shellac convert a natural polyester resin to a synthetic product [according to] the USDA-NOP rule as guideline. If the petitioner can document that no chemical change occurs in the Seedlac and purification is conducted in organic ethyl alcohol, then the process would be more compatible with organic systems. Overall, coatings are not essential for raw agricultural commodities, but only function to reduce weight loss (maintain a profit margin), enhance appearance (improve marketability at retail level) and provide a "fresh look" to the product. Usage levels generally are below 0.5% on a weight/weight basis.

Conclusion – Summarize why this material should be allowed or prohibited for use in organic systems.
I agree that impure shellac, also called Sticklac, appears to be a natural product that when further processed to Seedlac--minimal chemical modification has occurred. However, after treated with ethanol (I presume denaturated due to the cost of pure food grade ethanol) and clarification with activated carbon, which is not on the National List as documented in 7CFR 205.605, shellac is unquestionably synthetic. However, with modifications of its manufacturing operations with the use of organic ethyl alcohol and physical clarification with an approved processing aid, a strong argument can be made for its compatibility with organic handling operations.

Reviewer 1 Recommendation Advised to the NOSB:
The substance is: Synthetic

In a product labeled 95% organic
The substance should be: Prohibited (do not add to National List)

In a product labeled "made with organic (specified ingredients)"
The substances should be Allowed without further restriction

Reviewer 2 *[Ed.D Nutrition Education, Professor Emeritus nutrition and education, many publications, journal reviewer, Eastern US]*

Comments on Database
I find the database (Characterization and Status) to be reasonably complete and fairly accurate.

NOSB Processing Criteria Evaluation
1. It cannot be produced from a natural source and has no organic ingredients as substitutes.
This material IS from a natural source. Therefore (see below).

2. Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA.
I agree with the criteria evaluation.

3. If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations.
I agree with the criteria evaluation.

4. Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.
The primary purpose of shellac where NOSB is concerned is as an ingredient in sprays or dips designed to keep produce fresh longer. This would fit my definition of a preservative (the pharmaceutical uses are not relevant here). Although the 1999 TAP review said that "fruit waxes are generally not considered to be preservatives," it goes on to say (#6) that "these are non-food materials. . . being applied to food products in order to replace natural oils or waxes. . . or to otherwise preserve produce in its harvested state for a longer than natural period of time."

The criterion also says a material's primary purpose cannot be as a preservative OR to "recreate…colors, textures. . .lost during processing." This is surely a substance designed to replace something (a texture?) lost during processing.

5. Is Generally Recognized As Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP), and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.
The petitioner's file implies that the substance is GRAS. It is apparently not GRAS because of insufficient data on health effects.

6. Its use is compatible with the principles of organic handling.

… Regarding formulation, this specific form of shellac appears to be "natural" in its production. It is, however, applied to fruit in mixtures containing 55% to 98% other materials. It is unclear from the information provided whether there are enough allowed materials available to formulate a "natural" fruit coating from a "natural" shellac. If not, the acceptance of this material may be moot.

If such a coating can be formulated, is its application on organic fruit compatible with organic handling? I think not for several reasons. As described under criterion #4 above, the petitioned material clearly seems intended to serve one or more prohibited purposes, and in that sense be designed to compensate for deficiencies in handling fruit after harvest. To allow restoration--with shellac--of the waxy coating naturally present on citrus reduces the motivation to develop a method of cleaning citrus that does not remove its natural protective wax layer and thus retains its organic integrity.

As the 1999 review suggests, the preservative action of fruit waxes is not necessary for a sustainable agricultural system and may well encourage less sustainable systems involving long distance transport of agricultural commodities.

Finally, I am very uncomfortable with the idea of "waxing" fruit, not least because consumers have long viewed waxed fruits and vegetables as a symbol of how far from real food the marketplace has gone. Organic fresh fruits and vegetables are believed to be free from "processing." If consumers were fully informed by labeling when "organic" fruit was "shellacked," they might be somewhat reassured about their ability to get what they are paying for, but this seems like a slippery slope.

Since I have myself frequently use citrus peel as an ingredient, it is clear that the proposed material is both a preservative and an ingredient.

7. There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.

There are a number of ways to protect fruit freshness including various controlled atmosphere regimens. There are also a number of ways to produce fruit coatings, and the literature suggests that where fruits are concerned, some of these are better for the intended purpose of maintaining fruit quality than shellac-based coatings.

Conclusion:

See 4, 6, & 7 above

Reviewer 2 Recommendation Advised to the NOSB:

The substance is: Not Synthetic, and Non-Agricultural

In a product labeled 95% organic

The substance should be Prohibited (do not add to National List)

In a product labeled "made with organic (specified ingredients)"

The substances should be: Allowed only with additional restrictions (annotation)

Suggested annotation: Allowed only when labeled to indicate that a shellac coating has been added.

Reviewer #3 *[Ph.D. in food science and nutrition, minor in analytical chemistry. Scientific and technical consultant to the food, pharmaceutical, and supplement industries. Western US]*

Comments on Database

I find the database (Characterization and Status) to be reasonably complete and fairly accurate, with the following addition.

One concern: This petition is specific to fruit coating only, but shellac is used as a confectionery coating as well. Is there any additional information as to its use in confectionery? If not, it seems like the annotation needs to be specific for fruit coating or we need to review it for other uses from the outset. See annotation below.

NOSB Processing Criteria Evaluation

1. It cannot be produced from a natural source and has no organic ingredients as substitutes.

I agree with the criteria evaluation.

2. Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA.

I agree with the criteria evaluation.

3. *If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations.*

Additional supporting information or comments.

[Note added] references regarding allergenic potential (Hausen, 2001; Orton, D.I. et al. 2001).

4. Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.

I agree with the criteria evaluation.

5. Is Generally Recognized As Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP), and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.

I agree with the criteria evaluation.

6. Its use is compatible with the principles of organic handling.

I agree with the criteria evaluation.

7. There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.

I agree with the criteria evaluation. [Reviewer 3 supplied an additional reference, Bai 2001, which compared use of candelilla wax, carnauba-shellac, shellac, and polyethylene formulations on different varieties of apples. Shellac was more suited for Red Delicious, but less useful on lighter colored varieties. Candelilla wax did not give as shiny a coating, and did not cause anaerobic breakdown.]

Conclusion – Summarize why this material should be allowed or prohibited for use in organic systems.

This material on the whole seems to be compatible with organic production. However, I agree with the comments that it would be better for the consumer if there were a requirement for labeling of the fruit at retail somehow, especially with the two incidences that may indicate that there is allergenic potential (Hausen, 2001; Orton, 2001).

Reviewer 3 Recommendation Advised to the NOSB:

The substance is: Not Synthetic, and is Non-Agricultural

In a product labeled 95% organic

The substance should be Allowed only with restrictions (annotation).

Suggested annotation: "for coating of fruit only"

In a product labeled "made with organic (specified ingredients)"

The substances should be: Allowed without further restriction

[End of TAP Reviewer comments]

Conclusion:

The TAP Reviewers found that orange unbleached shellac is derived from natural sources, though one considered that the materials used in manufacturing rendered the substance synthetic and not compatible with organic standards. A second reviewer found that the uses of the material to extend shelf life, reduce water loss, and improve cosmetic appeal are not compatible with organic principles. The third reviewer found the material suitable for organic use, though expressed some concerns that consumers should be informed that products have shellac coatings applied, especially since there are some reports of allergenicity. All reviewers found that shellac could be allowed in a product labeled "made with organic ingredients" though one supports a restriction that the coating use clearly labeled.

References

** = included in packet*

* Ash, M., I. Ash. 1995. Handbook of Food Additives. Gower Publishers, Hampshire UK

Ayres, E.F. 1890. Preserving Fruit, &c. US Patent 437,323. Assigned (half) to Timothy Foster.

*Baldwin, E.A., M. Nisperos-Carriedo, P.E. Shaw, and J.K. Burns. 1995. Effect of Coatings and Prolonged Storage Conditions on Fresh Orange Flavor Volatiles, Degrees Brix, and Ascorbic Acid Levels. J. Agric. Food Chem. 43: 1321-1331.

*Bai, J., R. H. Hagenmaier, E. A. Baldwin. 2001. Coating selection for 'Braeburn' and 'Granny Smith' apples. Hortscience 36 (3):598. (abstract)

Budavari S. (ed) 1996. The Merck Index, 12th Edition. Merck and Co. Rahway NJ.

*Class J.B. 1991. Resins, Natural in *Kirk-Othmer Encyclopedia of Chemical Technology, 4th edition.* Vol. 20 pp. 291-303. Wiley Interscience Publ. NY.

EPA. 2001. Office of Pesticide Programs, Lists of Other (Inert) Pesticide Ingredients. http://www.epa.gov/opprd001/inerts/lists.html

*FDA, 1989. U. S. .FDA Proposed Rule. July 20, 1989. Shellac and Shellac Wax, Proposed Affirmation of GRAS Status with Specific Limitations as Direct Human Food Ingredients. Fed Reg. 54:112 pp31055-31059. (included in petition)

*FDA. 2001. US. FDA Center for Food Safety and Applied Nutrition. Microbiological Safety of controlled and modified atmosphere packaging of fresh and fresh cut produce. http:// www.cfsan.fda.gov/~comm/ift3-6.html

FDA 2002. EAFUS: A Food Additive Database 2002-FEB-08 http://www.cfsan.fda.gov/~dms/eafus.html

FDA 2002. U. S. Food and Drug Administration, Center for Food Safety & Applied Nutrition, Office of Food Additive Safety, Summary of all GRAS Notices http://www.cfsan.fda.gov/~rdb/opa-gras.html

*Hagenmaier, R.D., R.A Baker. 1994. Wax Microemulsions as Citrus Coatings. *J Agric. Food Chem*. 42: 899-902

*Hagenmaier, R.D 2000. Evaluation of polyethylene-candelilla coating for 'Valencia' organges. *Postharvest Biology and Technol* 19: 147-154.

Hagenmaier, R.D 2002. The flavor of mandarin hybrids with different coatings. Postharvest Biology and Technol*. 24: 79-87.

*Hallman, G.J. , N.O. Nisperos-Carriedo, E. A. Baldwin, C. A. Campbell. 1994. Mortality of Caribbean fruit fly (Dipter :Tehpritidae) immature s in coated fruits. *J. of Economic Entomology* 87: 752-757. (abstract)

*Hausen, B. M., G.C. Nist 2001. Shellac contact allergy. Dermatologisches Zentrum Buxtehude Stuttgart Germany, Aktuell Dermatologie Vol. 27:10 pp 315-318. (abstract in English)

*Kaplan,H. J. 1986. Washing, Waxing and Color Adding in *Fresh Citrus Fruits*, W.F. Wardowski, S. Nagy, and W. Grierson.pp 379-395. Avi. Publ.

*Kabra, K. N. 1983. *Dependence and dominance : political economy of a tribal commodity*. Indian Institute of public Administration, New Delhi, India. 196 pp. (abstract)

*Krause, K.P. R.H Muller. 2001. Production of aquous shellac dispersions by high pressure homogenisataion. *Internatl. Journal of Pharmaceutics*. 223: 89-92.

* Lau, O.L. 1998. Effect of growing season, harvest maturity, waxing, low O2 and elevated CO2 on flesh browning disorders in 'Braeburn' apples. *Postharvest Biology and Technol*. 14: 131-141.

*McGuire, R. G. 1999. Evaluation of shellac and sucrose ester fruit coating formulations that support biological control of post-harvest grapefruit decay. *Biocontrol Science and Technology* 9: 53-65.

*McGuire, R. G. R. D, Hagenmaier. 2001. Shellac formulations to reduce epiphytic survival of coliform bacteria on citrus fruit postharvest. *Journal of Food Protection* 64 (11) 1756-1760. (abstract)

*Orton, D.I., Salim A, Shaw S. 2001. Allergic contact cheilitis due to shellac. Contact Dermatitis. 44(4):250

*Saftener, R. A, W. S. Conway. 1999a. Postharvest Calcium infiltration alone and combined with surface coating treatments influence volatile levels, respiration, ethylene production and internal atmospheres of "Golden Delicious" apples. *J. Amer. Soc. Hort. Sci.*124: 553-558.

*Saftener, R. A,. 1999. The Potential of Fruit coating and film treatments for improving the storage and shelf-life qualities of "Gala" and "Golden Delicious" Apples . *J. Amer. Soc. Hort. Sci*. 124: 682-689.

*Sankaranarayanan, Y. 1989. Shellac for Food, Confectionery & Pharmaceutical Products. Publ. By Shellac Export Promotion Council, Calcutta.

*Singhania, S. 2001. Petition to USDA for Dewaxed Orange Flake Shellac, Renshell Exports Pvt. Ltd. Reseda, CA.

*Martin, J. 1982. Shellac, in *Kirk-Othmer Encyclopedia of Chemical Technology, 3rd edition.* Vol. 20 pp. 737-747 John Wiley and Sons, NY.

USDA / NOSB 1999. Waxes. Technical Advisory Panel review. Available at www.omri.org.

*Trezza, T. A., J.M Krochta. 2000. The Gloss of Edible Coatings as Affected by Surfactants, Lipids, Relative Humidity, and Time. *Journal of Food Science*: 6594) 658-661.

Viswanth, P.K. Kaushik, S. Chand, D.K. Pandey. 1994. The butea tree – for lac and rice production in India. *Agroforestry Today* 6:2, 10. (abstract)

*JEFCA (UN FAO / WHO Joint Evaluation Committee on Food Additives). 1993. World Health Organization, Toxicological Evaluation Of Certain Food Additives And Naturally Occurring Toxicants. Who Food Additives Series 30. The thirty-ninth meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Monograph 760. Shellac. Geneva http://www.inchem.org/documents/jecfa/jecmono/v30je15.htm. (submitted with petition)

*_____.1996. Summary Evaluaation by JEFCA on Food Additives. FAO. Geneva. Shellac (bleached).

This TAP review was completed pursuant to United States Department of Agriculture Purchase Order # 43-6395-0-2900A.