Carnauba Wax

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
Carnauba wax

Other Name:
Brazil wax, palm wax, ceara wax;
INCI name: *Copernicia cerifera* (carnauba) wax

Trade Names:
Carnauba Wax, Carnauba Wax Type 1, Type 3 or Type 4 Flakes, Powder or Lumps

CAS Numbers:
8015-86-9

Other Codes:
INS number 903, E number E903, EC Number 232-399-4

Summary of Petitioned Use

Carnauba wax is listed at 7 CFR Part 205.605(a) as one of two nonsynthetic waxes allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." There are no other specific restrictions on how carnauba wax may be used in the organic regulations.

Characterization of Petitioned Substance

Composition of the Substance:
Carnauba wax is an amorphous, complex mixture of several compounds, predominantly esters such as aliphatic esters, alpha-hydroxy esters and cinnamic aliphatic diesters. It also contains free acids, free alcohols, hydrocarbons and resins (European Food Safety Authority 2012) (Joint FAO/WHO Expert Committee on Food Additives 2006). It has anywhere from 0.5 -11% water (Bennett 1963). In its raw form, carnauba wax contains impurities in the form of unsaponifiable residues originating from the carnauba palm plant (Ministério da Agricultura, Pecuaria e Abastecimento, Gabinete de Ministro 2004). These comprise 50-55% of raw carnauba wax (Joint FAO/WHO Expert Committee on Food Additives 2006).

Source or Origin of the Substance:
Carnauba wax occurs naturally as an exudate from the leaves and buds of the palm tree *Copernicia cerifera*, also known as *Copernicia prunifera*, which grows almost exclusively in northeastern Brazil. It occurs as a fine powder on both young, upright, closed leaves, as well as more mature, pendant, open leaves. Brazilian technical regulations define the wax powder coming from these two types of leaves as A and B, respectively (Ministério da Agricultura, Pecuaria e Abastecimento, Gabinete de Ministro 2004). It is refined and then marketed in five grades or types designated as No. 1 through No. 5. The differing grades come from leaves of different ages and sizes. According to the FDA GRAS listing for carnauba wax at 21 CFR 184.1978, grades No. 4 and 5 make up the bulk of commercial U.S. trade. These consist of primarily C24 to C32 normal saturated monofunctional fatty acids and normal saturated monofunctional primary alcohols (Food and Drug Administration 2013). The differing grades of carnauba wax are commonly referred to in the literature and marketplace as Type 1, Type 2, Type 3, Type 4 and Type 5.

Properties of the Substance:
Carnauba wax is the hardest natural wax and has the highest melting point with the exception of some crude grades of ouricury wax[1] (Bennett 1963). Carnauba wax is tough, lustrous, brittle, and has a clean

[1] Ouricury wax is obtained from the leaves of the Ouricary Palm (*Syagrus coronate*) which grows in Northeastern Brazil. Its characteristics are similar to those of carnauba wax, but it is only available in brown color and is more difficult to extract from the leaves than is carnauba wax (NIIR Board of Consultants and Engineers 2011).

fracture. Its properties are outlined below in Table 1. Refined carnauba wax is classified into 5 grades or types, defined by the parameters shown in Table 2 (Ministério da Agricultura, Pecuaria e Abastecimento, Gabinete de Ministro 2004).

Table 1. Carnauba Wax Characteristics (from USP Monograph (U.S. Pharmacopeia 2013), Food Chemicals Codex (National Academy of Science 2004) and JECFA (Joint FAO/WHO Expert Committee on Food Additives 2006).

Property	
Form	Powder, flakes/scales, or lumps
Color	Pale yellow to dark brown depending on grade
Odor	Light, characteristic
Melting Range	80°-86°
Solubility	Insoluble in water; partially soluble in boiling alcohol; soluble in ether, chloroform and oils
Acid value	Between 2 and 7
Saponification value	Between 78 and 95
Ester value	Between 71 and 93
Residue on ignition	Not more than 0.25%
Unsaponifiable matter (impurities)	50-55%

Table 2. Classification of Refined Carnauba Wax, as defined by the Brazilian Ministry of Agriculture (Ministério da Agricultura, Pecuaria e Abastecimento, Gabinete de Ministro 2004), (European Wax Federation 2013).

Types	Coloration	Refinement Process	Humidity and Volatile Material (max. %)	Insoluble Impurities (max. %)	Ash (max. %)	Acid Value (min. | max.)		Melting Point (°C min.)	Saponification Index (mg KOH/g) (min. | max.)	
Prime 1 or Filtered Yellow	Light yellow	Filtration	0.5	0.1	0.2	2.0	6.0	83.0	78.0	85.0
Medium 2 or Filtered Extra Fatty	Light orange	Filtration	0.5	0.1	0.3	2.0	6.0	82.5	80.0	90.0
Clear 3 or Filtered Fatty	Dark orange	Filtration	0.5	0.1	0.3	4.0	10.0	82.5	80.0	90.0
Brown 4 or Filtered Grey	Dark brown	Filtration	0.5	0.1	1.0	4.0	10.0	82.5	80.0	90.0
Black 5 or Centrifuged Grey	Black	Centrifugation	0.5	1.0	1.0			82.5	80.0	90.0

<u>Specific Uses of the Substance:</u>

Carnauba wax is used in organic food handling and processing as a component of fruit coatings (Plotto and Narcisco 2006), candy coating (Weigand 2013) and as a component of an edible coating for nuts (Mehyar, et al. 2012). It can be used in food as a base for chewing gum and in soft drinks (Alves and Coelho 2006). Carnauba wax's function as a processing aid also includes use as a releasing agent (European Food Safety Authority 2012) and in defoamers, such as for use during washing of fruit and vegetables (OMRI 2013).

The GRAS listing for carnauba wax in 21 CFR 184.1987 does not stipulate any limitations on its use as an ingredient in food other than that it be used according to good manufacturing practices. Good manufacturing practices are specifically referenced for its use as an anti-caking agent, formulation aid, lubricant and release agent, surface finishing agent, in baked goods and baking mixes, chewing gum, confections and frostings, fresh fruits and fruit juices, gravies and sauces, as well as soft candy. Carnauba wax is listed by the Joint Expert Committee on Food Additives of the FAO/WHO (2006) for use as a glazing agent, bulking agent, acidity regulator, and carrier.

Carnauba wax is marketed for a myriad of other non-food applications. These include but are not limited to use in cosmetics, sunscreens, pharmaceuticals, nutraceuticals and gel caps, as well as in food packaging and cleaning products. It is used as shoe wax and as surface wax for airplanes and cars. It is also a common component of paper coatings, is found in printer ink and computer chips, and can be used for waterproofing materials such as laminated plywood (Koster Keunen 2011), (Foncepi 2013). It is used in dental floss, plastic films, adhesives, photographic materials, and many other areas (Alves and Coelho 2006).

Approved Legal Uses of the Substance:

Carnauba wax is a "Direct Food Substance Affirmed as Generally Recognized As Safe," or GRAS, according to FDA regulations at 21 CFR 184.1978. Its GRAS listing provides no limitation on its use in food other than current good manufacturing practices. Conditions for good manufacturing apply to carnauba wax's use as an anticaking agent, formulation aid, lubricant and release agent, and as a surface-finishing agent. The GRAS listing also identifies foods groups for which good manufacturing practices limit the level of carnauba wax as an ingredient. These include: baked goods and baking mixes, chewing gum, confections and frostings, fresh fruits and fruit juices, gravies and sauces, processed fruits and fruit juices, and soft candy.

Carnauba wax may also be used as an indirect food additive according to 21 CFR 175.320(b) (3) (iii). This listing allows its use as a component of coatings for food-contact surfaces of articles intended for use in producing, manufacturing, packaging, processing, preparing, treating, packaging, transporting or holding food, with no limitations.

The FDA 'Everything Added to Food in the US' database lists carnauba wax in Doc No. 1854.

Carnauba wax is also an inert ingredient eligible for use in FIFRA 25(b) Pesticide Products applied to food use and/or nonfood use sites (United States Environmental Protection Agency 2010).

Action of the Substance:

In its natural occurrence on the carnauba palm, which is adapted to dry regions, carnauba wax impedes water loss due to transpiration. It reflects light and protects the plant from fungal attacks (Alves and Coelho 2006). Used as a component of coatings, carnauba wax acts in a similar manner in post harvest treatment of produce: it reflects light giving the fruit a shiny appearance, reduces loss of moisture and mass, prevents fungal attack and postpones decay.

Carnauba wax, when formulated as part of a fruit coating, essentially functions to reduce gas exchange between the surface of the fruit and the atmosphere. This results in reducing the respiration rate and weight loss of the fruit. The reduced gas exchange is considered to happen in two different ways: the wax forms a physical barrier that the gas must permeate, and the coating fills openings in the fruit peel (Hagenmaier and Baker 1993). Hagenmeier and Baker (1993) found that some factors such as thickness of coating, and the waxiness vs. resinous qualities of the coating also affect the action of fruit waxes. For example, coating thickness is as important as type of coating for resistance to water vapor. Jacomino et al. (2003) found that a dilute concentration of carnauba wax coating maintains internal oxygen levels of fruit, which can also maintain flavor. However, coatings with high concentration of carnauba wax reduced gas exchange to the point of producing off flavors (Jacomino, et al. 2003).

Delayed decay from application of carnauba wax-based coatings has also been attributed to the gas barrier created which modifies the atmosphere in contact with the fruit. This has been reported to retard ripening and senescence, thereby reducing susceptibility of the fruit skin to infection by pathogens (Jacomino, et al. 2003). Carnauba wax coatings have relatively low oxygen and moisture permeability, though it is more permeable to O_2 and CO_2 than wood rosin and shellac coatings (Hagenmaier and Shaw 1992). The gas barrier also impedes oxidation of oils which in turn reduces rancidification of fatty foods such as nuts (Mehyar, et al. 2012).

Carnauba wax's role in the prevention of fungal attack in post-harvest fruit can also be attributed to antifungal properties beyond just creating a gas barrier. Cruz et al. (2002) found that proteins isolated from the various fractions of carnauba wax have antifungal enzymatic activity. These enzymes, chitinase and β-1,3-glucanases, can inhibit early growth of fungi and alter hyphal (threadlike filaments forming the mycelium of fungi) morphology of fungi growing in the presence of the proteins (Cruz, et al. 2002). Carnauba wax was observed in a separate study to be effective in controlling mycelial growth of *Coletotrichum musae* at a dose of 80 µL/mL under laboratory conditions (Chaves de Souza, et al. 2013). However, de Souza et al. also noted that some components that are formulated with carnauba wax to create emulsions may interfere with the antagonistic effect it has on some fungal contaminants.

Carnauba wax, when formulated into coatings, lends glossy appearance due to the presence of globules of fatty acids suspended in the applied emulsion (Hagenmaier 2004). However, wood rosin and shellac-based coatings are thought to offer the most sheen (Krochta, Baldwin and Nisperos-Carriedo 1994).

Combinations of the Substance:

Carnauba wax has a wide range of applications and, as a consequence, is commercially available in a variety of combinations. Carnauba wax used in fruit and vegetable coatings is always applied in the form of a microemulsion made with a fatty acid and a basic counterion (Plotto and Narcisco 2006). These produce an anionic emulsifier in which the carnauba wax is dispersed. Types of fatty acids used include oleic, linoleic, palmitic, myristic or lauric acid. The basic counterion may be hydroxides of sodium,potassium salts, or ammonium, morpholine (Hagenmaier 1998) or, in the past, triethanolamine (Krochta, Baldwin and Nisperos-Carriedo 1994). Because carnauba wax is only used as a fruit coating in combination with other substances, the efficacy and compliance of the other substances must also be considered.

Morpholine is said to be the best emulsifier of carnauba wax (Wartanessian 2013); it is commonly used to ionize fatty acids in many wax emulsions. Hagenmaier (2004) tested over 150 different formulations for carnauba wax microemulsions. He found that high quality emulsions using ammonia as the base were successful when food-grade oleic acid was used along with myristic and/or lauric acid, whereas emulsions using morpholine as the base could be made with only oleic acid as the source of the fatty acid, suggesting morpholine's efficiency as an emulsifier (Hagenmaier 2004).

Carnauba wax emulsions may also contain an antifoam such as silicon dioxide, an allowed synthetic substance under the USDA organic regulations at §205.605(b), or polydimethylsiloxane (Plotto and Narcisco 2006).

Raw carnauba wax is sold without any additional ingredients such as stabilizers or preservatives (Wartanessian 2013). Buyers then formulate the carnauba wax into fruit coatings and other products. There are commercially available fruit coatings in which carnauba wax is combined only with substances permitted on the National List (OMRI 2013).

Fruit coatings in which carnauba is the only wax ingredient in the formulation are available (Krochta, Baldwin and Nisperos-Carriedo 1994). However, combinations of carnauba wax with other waxes and coating materials are even more common. For example, carnauba wax may be combined with beeswax, candelilla wax, wood rosin or shellac to increases the hardness and melting point of the fruit coating. It is also added to other waxes to increase toughness and luster and to decrease stickiness, plasticity and crystallizing tendencies (Bennett 1963).

In application as a defoamer in fruit and vegetable washing, carnauba wax is commercially available as an emulsion in combination with an oil (OMRI 2013).

A patent for Natural Technology International Limited (Laha Fu, An Sike and Waldman 2013) provides a myriad of possible combinations proposed for fruit waxes on organically produced produce. The following table summarizes the possible combinations covered by the patent:

Table 1: Selection of possible components for edible coatings patented for organic fruits

Natural Wax	Alkaline Agent	Botanical extracts[1]	Emulsifier[1]	Vegetable Oil[1]	Protective Colloid[1]
Wood rosin	Sodium (bi)/carbonate	Rosemary	Nictotinic acid	Soybean	Casein
Beeswax	Potassium (bi)/carbonate	Sage	Pantothenic acid	Palm	Gelatin
Candelilla wax	Sodium hydroxide	Green tea water	Ascorbic acid	Corn	Lecithin
Carnauba wax	Potassium hydroxide	Eucalyptus	Wood rosin	Olive	Xanthan gum
Berry wax		Lavender	Shellac	Linseed	Alginic acid

[1]Not an exhaustive list

Status

Historic Use:

Carnauba wax was reviewed and voted for listing on the National List by the NOSB in 1996 under the general term "fruit waxes." It is currently listed at section 205.605(a) of the National List of Allowed and Prohibited Substances under Waxes – nonsynthetic, along with one other nonsynthetic wax, "Wood resin." Historical use in organic food processing is as a component of fruit and vegetable waxes and in candy coatings.

Organic Foods Production Act, USDA Final Rule:

Carnauba wax does not appear specifically in OFPA. It is permitted as a nonagricultural (nonorganic) substance allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))"per 7 CFR §205.605(a) as Waxes –nonsynthetic (Carnauba wax; and Wood resin [rosin]) (USDA 2013).

International

Carnauba wax is currently permitted under all four of the most prevalent organic standards (U.S., EU, Canada, JAS), for various uses and with various provisions as outlined below.

Canada - Canadian General Standards Board Permitted Substances List –

Carnauba wax is allowed for use in processed organic products per CAN/CGSB 32.311 Table 6.4 Non-organic Ingredients not Classified as Food Additives as follows: "Waxes – non-synthetic only: a) carnauba wax and b) wood resin (processing product of resin component)."

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

Carnauba wax is permitted by the CODEX Alimentarius per Table 4: "Processing Aids Which May Be Used For The Preparation Of Products Of Agricultural Origin Referred To In Section 3 Of These Guidelines" under "For plant products, as a releasing agent."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Annex VIII B – Carnauba wax is allowed as a releasing agent. It has also been recommended by the European Commission's Expert Group for Technical Advice on Organic Production (EGTOP) (2012) as a food additive (glazing agent) that is in line with the objectives, criteria and principles of organic farming as laid down in Council Regulation 834/2007, and should be included in Annex VIII A with the following restrictions:
"1. As a glazing agent for confectionary only. 2. Only in organic quality."
EGTOP recommends that the authorization of carnauba wax in Annex VIII B should also be amended to require its use only in organic form. Additionally, the EGTOP has stated that solvent extraction with heptane as well as bleaching with hydrogen peroxide is not permitted in the production of organic carnauba wax (Expert Group for Technical Advice on Organic Production (EGTOP) 2012).

Japan Agricultural Standard (JAS) for Organic Production
Carnauba wax is included in JAS Notification No. 1606 of the Ministry of Agriculture, Forest and Fisheries, Oct. 27, 2005, revised 2012: Table 1 Food Additives: "Carnauba wax. Limited to be used for processed foods of plant origin as separating agent."

International Federation of Organic Agriculture Movements (IFOAM) –
Carnauba wax is permitted for use under IFOAM Norms for Organic Production and Processing. It appears in Appendix 4 – Table 1: List of Approved Additives and Processing/Post-Harvest Handling Aids. IFOAM also endorses USA Organic Regulation, EU Organic Regulation, and Japan Organic Regulation, all of which permit the use of carnauba wax in organic food processing.

Evaluation Questions for Substances to be used in Organic Handling

<u>Evaluation Question #1:</u> 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)).

To produce carnauba wax, leaves are cut from the carnauba palm tree, *Copernicia cerifera* during Northeastern Brazil's dry season in the latter part of the year. Two types of leaves are obtained: the younger, closed leaves that produce a higher quality, lighter wax with fewer impurities, and the older, open leaves from which darker wax is produced. The young, closed leaves are separated from the rest of the cut leaves and all are packed in fagots and dried in the sun for 6-12 days. They are then beaten or scraped, either manually or mechanically, until the wax falls off as a fine powder. The wax is collected and processed according to the technology available and the desired end product.

Traditionally, the wax is melted with steam or heated in water to around 120°C. Solvents may be used instead of or in addition to water. Alves and Coelho (2006) identified turpentine, benzene and ether as possible solvents. The wax is then cooled and filtered in a filter press or through filter cloth. The resulting material may be returned to boil and filtered again. Filtering removes impurities. The wax obtained is then cooled and dried in a tank or put in sheets to dry.

In industrial settings, the wax powder similarly undergoes extraction using water and/or solvents such as heptane, turpentine, benzene, or ether and is heated to 100- 120°C. In some cases, rice stalks are added to facilitate the extraction of the wax. The material then undergoes distillation in a concentrator where the solvent and water evaporate, leaving the liquid wax behind. The wax is cooled. Clay may be added to the cooling wax to absorb impurities and chlorophyll. Alternatively, clay may be added to the wax-solvent solution prior to distillation. The material is filtered through fine paper or fabric to remove the clay and clarify the wax. The wax may also be clarified via centrifugation. Hydrogen peroxide may be added to bleach or clarify the wax further. For example, Type 3 carnauba wax goes through clarification to produce a lighter color than Type 4 wax, which otherwise has the same origin and processing. In some cases, the wax goes into a scaler where thin layers of solid wax fall into a container and break into small pieces to produce flakes. Finally, the wax is packaged. (Alves and Coelho 2006), (Carvalho and Gomes 2008), (Foncepi 2013), (Wartanessian 2013), (Expert Group for Technical Advice on Organic Production (EGTOP) 2012).

One patent (Jacob 1995) describes a refining process for carnauba wax as follows: the raw wax is sieved, dissolved in aliphatic solvents of narrow distillation range (no higher than 85ºC), namely, naphthas, heptanes or hexanes, then purified mechanically by either filtering or centrifuging to remove most impurities. The purified solution is then reacted with bleaching earths or fuller earths at variable proportions depending on the end product sought, up to one and a half times the wax content of the solution. The solution is then filtered to recover the bleaching earth and distilled to remove the solvent, leaving a pure wax. The wax may be finished by reacting with hydrogen peroxide to obtain the color desired.

According to one certifier, no synthetic solvents are used in the extraction of carnauba wax that is certified organic., but certified organic carnauba wax may be filtered using diatomaceous earth as a filtration aid and/or clarified with hydrogen peroxide (Vailati 2013).

In order to formulate the wax into an emulsion that may be applied to fruit, the water-to-wax or wax-to water method may be used (Hagenmaier 1998). In the water-to-wax method, wax and the other ingredients are heated to 10-20º C above the melting point of the wax and then hot water is slowly added with stirring, after which the mixture is cooled to 50º C in a water bath with stirring. The water-to-wax method is similar except that the ingredients are poured into the hot water being rapidly stirred and the mixture is then cooled (Hagenmaier 1998). Ingredients can also be added sequentially (OMRI 2013).

<u>Evaluation Question #2:</u> 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.

As described earlier, carnauba wax may be chemically extracted from leaves of the carnauba palm using solvents. Solvents such as benzene are typically liquids that dissolve another substance, resulting in a solution. Solvents are selected by the specific chemical properties that enable the solute to dissolve. A solution consists of all ingredients uniformly distributed at a molecular level (Ashenhurst 2013). Thus, when the raw carnauba powder that has been manually extracted from the leaves is placed into benzene or other solvent, the wax dissolves into the solvent. The solvent is then removed from the wax solution by distillation, leaving the carnauba wax solution. The following distilling conditions are said to recover all of the solvent from the wax: temperature between 60 and 80ºC and negative pressure of 600 mmHg. Therefore, although the extraction process is chemical, no chemical changes occur in the various components of the carnauba wax solution. As noted, the solvent is removed by evaporation or vacuum-distillation, which are both physical processes.

The bleaching earths added to the wax solution during processing are absorptive clays such as bentonite or montmorillonite. Due to clay's enormous surface area and charged sites, many types of organic molecules are attracted to and bind to the planar surfaces and edges of clay crystals (Brady and Weil 2002). Thus, when used as a bleaching agent, the clays absorb pigments and chlorophyll existing in the raw material via physical contact (Jacob 1995). This does not change the fundamental chemistry of the wax, and the clays are removed by filtration.

As noted above, hydrogen peroxide is sometimes used as a final clarifying agent to bleach carnauba wax. Hydrogen peroxide functions as an oxidizing agent, breaking apart pigment molecules found in wax. In his patent, Jacob (1995) notes that in order to obtain acceptable standards for color, the chemical bleaching step sometimes requires large amounts of hydrogen peroxide and this may modify some chemical constants of the product. However, the process proposed in his patent claims to not change the chemical parameters of the product. Another patent describes the use of mild chemical reagents, namely hydrogen peroxide in combination with alkali materials, to clarify the color of wax, and claims that with the method proposed the wax retains its desirable natural characteristics and is substantially unchanged, except as to color (Scheller 1940). Scheller's patent (1940) noted that the wastewater resulting from bleaching the wax was neutral in reaction, which indicates no substantial decomposition of the wax. Therefore, it is possible that the clarification of carnauba wax with hydrogen peroxide only affects pigmentation; however, the literature is not conclusive as to whether or not it may react to some degree with other components of the wax. No residual hydrogen peroxide remains in the final carnauba wax product due to its high volatility (Vailati 2013).

Historically, carnauba wax has not been considered an "agricultural product" as defined by §205.2. It is listed at §205.605(a) as a non-agricultural substance and is not marketed in the US as a stand-alone product for human or livestock consumption. However, it is possible that carnauba wax could be considered agricultural based on the definition of "agricultural product" at §205.2. It is derived from a plant, the carnauba palm, and does have intended uses for "human consumption." FDA regulations permit its use on food, and certified organic carnauba wax is available in the marketplace. There are seven operations in Germany, Brazil, and the U.S. that produce or handle organic carnauba wax according to the 2012 list of certified USDA organic operations (National Organic Program 2012).

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

Carnauba wax is currently classified as nonsynthetic and appears at 205.605(a) as a nonsynthetic wax permitted as an ingredient in or on organic processed foods.

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.

Carnauba wax is classified as GRAS. It is listed at 21 CFR 184 – Direct Food Substances Affirmed as Generally Recognized As Safe, Subpart B, Sec. 184.1978.

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 2013) Carnauba wax is primarily used as an ingredient in fruit coatings. The primary function of fruit coatings is to regulate gas exchange between the fruit and the environment, thereby reducing weight loss during shipping and storing (Hagenmaier and Shaw 1992). However, studies have shown that fruit coatings reduce decay incidence and delayed ripening. Mehyar et al. (2012) found that carnauba wax used in fruit coatings protects against decay and rancidification of oils. It has also been reported to prolong ripening and reduce incidence of disease in various types of produce (Gonçalves, et al. 2010). In Hagenmaier and Shaw's (1992) review of the literature, it is clear that fruit waxes (made with all types of substances) have several functions that prevent spoilage such as forming a diffusion barrier to gases and a barrier to water vapor. Cruz et al. (2002) found that proteins in carnauba wax have enzymatic activity which can inhibit fungal growth. However, there is a lack of literature specifying that carnauba-based fruit waxes specifically act as a preservative.

Evaluation Question #6: 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)).

Carnauba wax coatings' primary function is not to recreate or improve flavors, colors, textures or nutritive value lost in processing but rather prevents or delays the loss of nutritive value, change in texture, and color of fruit. Similarly, when used in candy coatings, as an anticaking agent, release agent or defoamer, the function of carnauba wax is not to improve flavors, colors, textures or nutritive value of food. It does improve appearance when used in coatings by lending increased shine to fruit and candy surfaces but does not affect coloration. It allows some exchange of gases and, depending on its concentration in the fruit wax, does not greatly affect respiration rate or production of ethylene. Carnauba wax coatings maintain fruits' firmness longer, reduce loss of mass, and retard ripening and senescence, thereby reducing susceptibility of the skin to infection by pathogens (Jacomino, et al. 2003).

One of the characteristics that carnauba wax fruit coatings impart is sheen to the fruit surface (Krochta, Baldwin and Nisperos-Carriedo 1994). However, this is not due to the loss of shine during processing. Another main function fruit waxes provide is a waxy barrier to prevent the loss of water vapor. Lin and Zhao (2007) note that many fruits have a natural waxy cuticle that might be removed during post-harvest activities for which applying a fruit wax would replace its natural waxy cuticle. Waxing has been shown to retain firmness as well. The literature shows that fruit waxes can prevent loss of volatile flavor components while on the other hand, fruit waxes with high gas impermeability have been known to contribute to unfavorable flavors. Since fruit waxes inhibit gas exchange, their use can lead to anaerobic respiration and elevated ethanol and acetaldehyde contents, leading to off-flavors (Hagenmaier and Shaw 1992; Lin and Zhao 2007). Jacomino et al. (2003) noted that a high-concentration emulsion of carnauba wax contributed to off flavors in stored guavas, and recommended further evaluation of dilutions in order to aviod this result.

Evaluation Question #7: 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 carnauba-based fruit waxes themselves impart nutritional quality to food. Jacomino et al. (2003) reported that coating guavas with carnauba-based wax emulsions had little effect on total soluble solids, total titratable acidity and ascorbic acid contents. The study found that coatings with a high concentration of carnauba wax can produce undesirable off flavors due to an increase in internal CO_2 and decrease in O_2, and attributed this effect to the possible initiation of fermentation. Mehyar et al. (2012) found that coatings of whey protein isolate, pea starch and carnauba wax reduced the oxidative and hydrolytic rancidity of walnuts and pine nuts stored at room temperature for 12 days, but did not suggest any nutritional value inherent in the coating. Generally carnauba wax fruit coatings are not intended to impart nutritive value to food. However, alternative substances being investigated have been shown to be vehicles to enhance nutritional value. For example, xanthan gum coatings carry a high concentration of calcium and vitamin E, and when used as a fruit coating could effectively fortify fresh fruits (Krochta, Baldwin and Nisperos-Carriedo 1994).

Evaluation Question #8: 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 US Pharmacopeia (2013) Monograph for carnauba wax lists heavy metals, by Method II, as 20 µg/g. The Joint Expert Committee on Food Additives Monograph (1998) reports a lead level of not more than 2 mg/kg for carnauba wax. A review of several MSDS and technical sheets for carnauba wax reported heavy metals at a level of less than 20 ppm. None of the literature reviewed in this report indicates that carnauba wax contains heavy metals or other contaminants in excess of FDA tolerances.

Evaluation Question #9: 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 harvest of carnauba wax leaves has been reported to not cause harm to the environment because the tree replaces the cut leaves the following year (Alves and Coelho 2006). Also, once the wax has been removed from the cut leaves, the leaves may be further used to make other products such as hats, brooms or roof thatching (Alves and Coelho 2006).

EGTOP (2012) reported that there are no intensively managed plantations, but the palm occurs naturally in high numbers in poor soils. As the stands are harvested regularly, the Group expressed no environmental concerns regarding the production of carnauba wax from the carnauba palm (Expert Group for Technical Advice on Organic Production (EGTOP) 2012).

The manufacturing of carnauba wax does require electricity, intensive water use, burning of wood which may contribute to deforestation and produces CO_2, as well as the burning of diesel fuel in transporting the material (Carvalho and Gomes 2008).

The use of solvents in the extraction process is a main area of potential environmental impact. Alves and Coelho (2006) reported the implementation of technologies to increase efficiency, including the use of vacuum distillation in the extraction process in order to recover the solvent. Carvalho and Gomes (2008) explain that in the extraction process, water and solvents are both separated from the wax through evaporation by heating. The water is then density separated from solvent and both are recovered for reuse. The same report suggests that an estimated loss of solvent during the whole carnauba wax production process is on the order of 5%.

Other waste products from the manufacture of carnauba wax are non-toxic, such as clays, impurities from the clays, filter fabric, and bio-degradable rice stalks. A modest amount of plastic packaging is another potential environmental contaminant resulting from carnauba wax's use (Carvalho and Gomes 2008).

Evaluation Question #10: 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)).

A recent opinion (2012) on the use of carnauba wax as a food additive was published by the European Food Safety Authority's (EFSA) Panel on Food Additives and Nutrient Sources added to Food (ANS). It reported that carnauba wax is not expected to be significantly absorbed from the diet and, if hydrolyzed, its major components could be absorbed and incorporated into normal cellular metabolic pathways. The Panel reported no concern for genotoxicity, subchronic, reproductive, nor developmental toxicity from carnauba intake. Chronic toxicity and carcinogenicity studies were not available. The Panel did not establish an ADI level because long-term toxicity data is lacking. Overall, the EFSA Panel concluded that exposure to carnauba from the proposed uses (which include use as a fruit coating) were within sufficient margins of safety compared to the No Observed Adverse Effect Levels (NOAELs) identified for carnauba wax; thus, continued use of the wax as a food additive would not be a safety concern (European Food Safety Authority 2012).

The WHO's International Programme on Chemical Safety (1993) reported no acute toxicity studies or long-term carcinogenicity studies. Several short term studies showed no significant difference between animals fed carnauba wax in their diets at various concentrations versus controls, other than elevated free fatty acid levels in male dogs, and these were within normal range for the species. In reproductive studies, no effects on reproduction parameters were observed after feeding carnauba wax to pregnant rats at levels up to 1% of the diet. Negative mutagenicity results were observed in 5 of 6 studies, and the 6^{th} showed inconsistent changes. Results from this study indicated that there were no significant changes in body weights of pregnant dams during gestation; no significant differences in reproduction data among test groups; and no dose-related effects of carnauba wax on skeletal or soft tissue development in fetuses (International Programme on Chemical Safety, WHO 1993). Based on their studies, the FAO/WHO Expert Committee on Food Additives (JECFA) set an Acceptable Daily Intake (ADI) of 7 mg/kg bw/day for carnauba wax. Recommended application rates for at least one commercially available carnauba-based fruit coating would translate into approximately 158 mg/kg carnauba wax on apples and citrus fruit. Taking into account the bodyweight factor of the ADI, this amount would mean a person weighing 23kg (~50 lbs) could consume a kilogram (2.2 lbs) of the coated fruit per day without exceeding the ADI.

The US Pharmacopeia (2013) Monograph for Carnauba Wax notes that it meets the requirements for residual solvents. In the case of benzene, a Class 1 solvent (the most hazardous), the concentration limit is 2 ppm in drug products (U.S. Pharmacopeia 2013). Although the Maximum Contaminant Level for benzene in drinking water as set by the EPA under the Safe Water Drinking Act is 5 ppb (United States Environmental Protection Agency 2013), the literature reviewed in this report suggests that benzene or other residual solvents do not remain in the final carnauba wax product.

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

For preventing the reduction of fruit weight - the primary function that fruit waxes provide – the literature provides very little evidence towards effective alternatives to waxes. Rather, studies have shown that alternating 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 temperature, 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).

Carnauba-based fruit waxes have been shown to be effective in controlling the advancement of fungal disease in post-harvest produce (Cruz, et al. 2002; Chaves de Souza, et al. 2013). Carnauba wax-based coatings have also 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 56°C 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. Other alternatives include the use of ozone gas and chlorine sanitizing agents (Mari, Bertolini and Pratella 2003) and several methods not permitted by organic regulations including use of fungicides and irradiation (Gonçalves, et al. 2010).

Carnauba wax can also be used as a release agent. The FDA defines release agents at 21 CFR 170.3(o)(18) as "substances that are added to food contact surfaces to prevent ingredients and finished products from sticking to them." Release agents may come in the form of film forming lubricating oils, solid lubricants, waxes or fluids that prevent sticking. These are distinct from permanent non-stick coatings which lower surface energy to reduce sticking rather than relying on the boundary layer created by a non-permanent release agent (Packham 2002). However, there are many substances that can be used alone or in combination as release agents, and the literature reviewed in this report suggests that the use of release agents in food processing versus permanent non-stick coatings is common.

Other uses of carnauba wax such as in candy coatings, as an anticaking agent or defoamer are common in practice but not widely documented in the literature. Because applications of these types of uses are so varied, assessment of alternative practices that would make the use of carnauba wax unnecessary in other capacities besides fruit wax would have to take into account the specific needs of the application in question.

Evaluation Question #12: 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)).

The substance carnauba wax is itself a natural, nonsynthetic material.

There are primarily four different nonsynthetic substances that may be used in place of carnauba wax as a component of fruit waxes: orange shellac, wood rosin, beeswax, and candelilla wax. Each has their own positives and negatives for various factors, including shine, permeability, cost, etc. Of these four, only orange shellac and wood rosin are permitted as non-organic ingredients in fruit waxes used on organic fruit. Otherwise, organic beeswax and candelilla wax would be required for use on organic fruit. See question 13 below for more complete information on beeswax. Figure 1 demonstrates that different types of fruit coatings affect internal gas and ethanol concentrations in four apple cultivars.

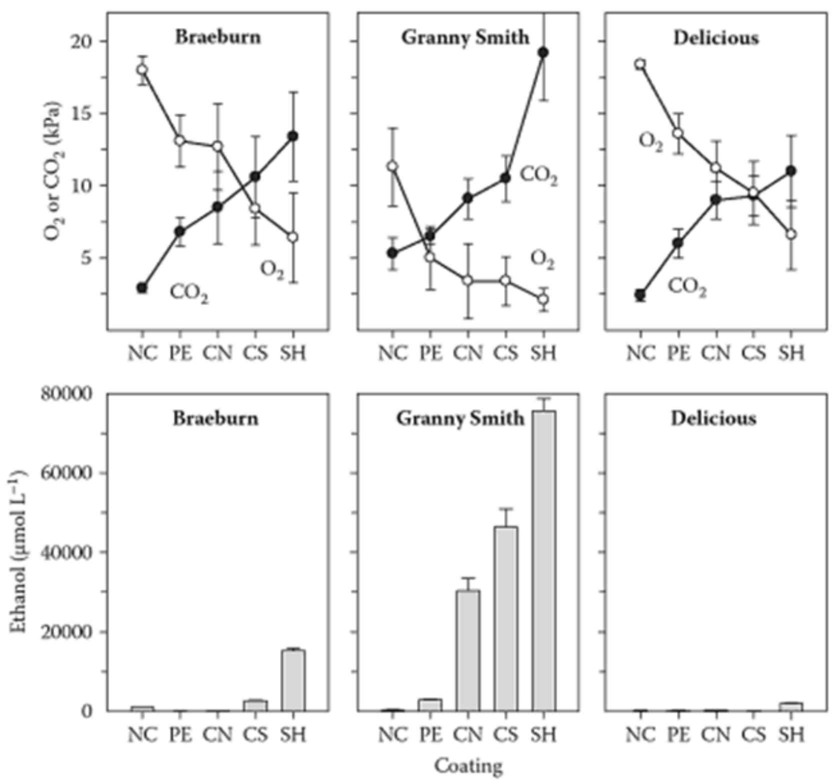

Figure 1: Internal gases (top) and ethanol concentrations (bottom) of three apple cultivars after 5 months of room temperature storage then coated and stored at 20° C for two weeks. (NC – No Coating; PE – Polyethylene, CN – Candelilla; CS- Carnauba – shellac; SH – shellac). (Krochta, Baldwin and Nisperos-Carriedo 1994)

A number of other nonsynthetic 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, pea starch, chitosan and rice bran wax (Hagenmaier 1998; Krochta, Baldwin and Nisperos-Carriedo 1994; Bai, et al. 2003; Park 1999; Mehyar, et al. 2012). However, there is very little literature to suggest that these are suitable as complete replacements for carnauba wax. Natural materials used as fungicides to control postharvest decay have been explored, including flavor compounds, acetic acid, jasmonates, glucopsinolates, propolis fusapyrone and deoxyfusapyrone, chisotan and essential oils (Tripathi and Dubey 2004; Mari, et al. 2003). However, the commercial development of such materials is in its infancy; more studies on efficacy, toxicity and effects on organoleptic properties of food, as well as registration of such products, are needed (Tripathi and Dubey 2004). Microbial agents are yet another potential alternative to the use of fruit coatings in the control of postharvest diseases; however, their use is reported to be limited due to inconsistent results and decreasing efficacy (Tripathi and Dubey 2004; Mari, et al. 2003).

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 take into account the need for other components to enhance the performance of the primary wax substance.

Orange shellac

Orange shellac appears on §205.606 as an agricultural substance that is permitted for use as a nonorganic ingredient when the organic version is not commercially available. It is a major component in coatings intended for all kinds of fruits. Commercial waxes containing shellac are used to coat pears, apples, (Hagenmaier and Shaw 1992), mango, papaya, and avocado. It is also used as an ingredient in candy coatings and pharmaceutical casings. Shellac is considered a resin and so permeability is very low and it is moderately resistant to water vapor. In general, shellac coatings dry fast, coat well, and produce a good sheen. However, they may whiten where commodities go through several temperature and humidity changes that cause the fruit to "sweat." Therefore, they are not as useful for fruit that is coated for export (Krochta, Baldwin and Nisperos-Carriedo 1994). It should be noted however that the literature suggests that shellac is often formulated with other waxes such as carnauba, wood rosin, beeswax, and candelilla in order to produce the most advantageous characteristics (Dou, Ismail and Petracek 1999, Hagenmaier and Shaw 2002, Lin and Zhao 2007). Therefore, its use as an alternative to carnauba wax depends also on the availablility of other substances for further formulation in edible coatings.

Wood Rosin

Wood rosin is produced from pine stump wood via solvent extraction and fractional distillation to remove volatile terpene oils. The remaining raw wood rosin is further refined and purified by a liquid fractionation process (Merck 2013). Wood rosin is listed jointly with carnauba wax at §205.605(a) as a natural wax allowed for use as an ingredient in or on organic food. Wood rosin is used in organic food processing exclusively as a fruit coating and, like carnauba wax, is always formulated with other ingredients for this purpose. Combinations with other ingredients may include shellac, carnauba, emulsifiers, plasticizers, anti-foam agents, surfactants and preservatives (Krochta, Baldwin and Nisperos-Carriedo 1994). When used as a component of fruit coatings, wood rosin reduces gas exchange more than does carnauba wax; however, it is not as effective at preventing water loss (Hagenmaeier and Baker 1994). Wood rosin is suggested to best provide sheen to coated fruit (Krochta, Baldwin and Nisperos-Carriedo 1994). When considering wood rosin for use as an alternative to carnauba wax, its combination with other substances in order to formulate it into a fruit wax must also be taken into account.

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 (Krochta, Baldwin and Nisperos-Carriedo 1994) (Hagenmaier and Baker 1993) (Purvis 1983) (Bosquez-Molina, Guerrero-Legarreta and Vernon-Carter 2003). 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 effects on color retention of the peel. For exmaple, 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[2] 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

[2] Saucedo-Pompa, et al. (2009) compared three microemulsions treatments of candelilla wax and ellagic acid at three different concentrations on avocado.

based fruit coatings are often formulated with other components such as carnuaba wax, wood rosin, 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 carnauba wax 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)).

As mentioned, carnauba wax is available in organic form, unlike other alternative fruit coating materials such as wood rosin and orange shellac. 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. Carnauba wax is also formulated in products compliant for use as fruit waxes on organic foods (OMRI 2013).

Of the alternatives discussed in Question 12 above, beeswax and vegetable oils are the only other alternatives that are currently commercially available in organic form (National Organic Program 2012).

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, 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. Baldwin (1994) found that beeswax emulsions were more effective than carnauba in retarding moisture loss. Beeswax has also been found to have anti-browning effects on cut fruit[3] (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, 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 carnauba wax without the availability of other compliant components. Further, beeswax may be considered an issue for vegan diets. There are currently 27 certified organic sources of beeswax. (National Organic Program 2012).

Vegetable oils

Vegetable oils used as fruit coatings are reported to be less effective barriers to water than waxes (Krochta, Baldwin and Nisperos-Carriedo 1994).

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[3] Perez-Gago, et al. (2003) compared different formulas of beeswax and whey protein isolate to determine the weight loss and color changes. The study did conclude that different contents of beeswax influence browning effects, but it was not determined whether the whey protein or beeswax was primarily responsible for the effects.

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