Wood Rosin

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
Rosin, wood rosin

Other Name:
Dark wood rosin, flaked resin, colophony, Greek pitch

Trade Names:
Belro, Pexite, Vinsol

CAS Numbers:
8050-09-7

Other Codes:
E 915 (esters of colophony)

Summary of Petitioned Use

Wood rosin [resin] 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 wood rosin may be used otherwise in the organic regulations.

Characterization of Petitioned Substance

Composition of the Substance:

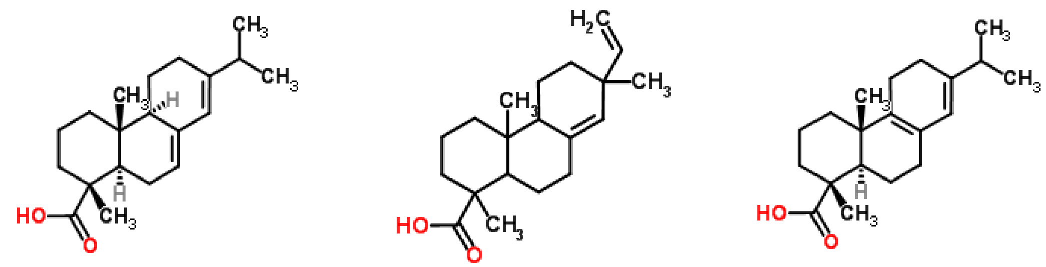
Wood rosin is currently erroneously listed at 205.605(a) as "wood resin." Wood resin is the raw material exuded by coniferous trees before it undergoes distillation and refinement steps as described in this report (Langenheim 2003).

Wood rosin is a complex organic mixture composed of rosin acids, oxidized and modified forms of these, and neutral and colored constituents associated with dark rosin. Dark wood rosin is composed of rosin-type resin acids, oxidized and otherwise modified forms of these materials, and a minor amount of the neutral and colored constituents. Vinsol is the highly refined and distilled components of wood rosin (Pinova 2013). The literature conflicts on the precise chemical composition of wood rosin: according to Krochta, et al. (1994), wood rosin is about 90% abietic acid ($C_{20}H_{30}O_2$) and its isomers and 10% dehydroabietic acid ($C_{20}H_{28}O_2$). Table 1 shows another breakdown of the chemical components of wood rosin:

Table 1: Composition of Wood Rosin (adapted from Pine Chemicals Association, Inc. (2004))

Components	Percentage
Pimaric acid	3%
Palustric acid	10%
Isopimaric acid	11%
Abietic acid	45%
Dehydroabietic acid	8%
Neoabietic acid	7%

Figure 1: Molecular structures for abietic, pimaric, and palustric acids (Royal Society of Chemistry 2013) .



Abietic acid Pimaric acid Palustric acid

Source or Origin of the Substance:

Wood rosin is the resin derivative from Longleaf (*Pinus palustris*) and Slash pine (*Pinus elliottii*) stumps. It is extracted with a solvent and fractionally refined to yield the final commercial ingredient(s). Wood rosin is differentiated from pine oil, terpene, and other oleo-resins as the non-volatile portion of the resinous material found in Longleaf and Slash pine stumps (Beglinger 1958). It is currently only manufactured by Pinova Solutions, Inc. based in New Brunswick, Georgia (Merck 2013).

The term 'rosin' is used to reference a variety of substances extracted from pine trees. The Agricultural Marketing Service (AMS) of the USDA (Part 160 – Regulations and Standards for Naval Stores) standardizes the definition of the following rosin substances in 7 CFR §160.12(emphasis added):

> (a) Rosin within the meaning of the act and the provisions in this part shall be designated as ''gum rosin,'' ''wood rosin,'' or ''tall oil rosin,'' as the case may be. (b) The designation ''gum rosin'' shall refer to the kind of rosin remaining after the distillation of gum spirits of turpentine from the oleoresin (gum) obtained from living pine trees. (c) *The designation ''wood rosin'' shall refer to the kind of rosin recovered after the distillation of the volatile oil from the oleoresin within or extracted from pine wood by any suitable process, followed by any necessary further refinement.* (d) The designation ''tall oil rosin'' shall refer to the kind of rosin remaining after the removal of the fatty acids from tall oil by fractional distillation, and having the characteristic form and appearance and other physical and chemical properties normal for other kinds of rosin.

Rosins also have grade designations, as stipulated by 7 CFR §160.13, from highest to lowest by the following letters: XC, XB, XA, X, WW, WG, N, M, K, I, H, G, F, E, D, B. In addition, the letters OP are used to designate the grade of opaque rosin, and the letters FF are used to designate the grade of normal wood rosin. ASTM standard D509 is a standard test method for sampling and grading rosin (ASTM International 2006).

Properties of the Substance:

Wood rosin is available in two commercial forms: solid and molten. It has a low ash content and wide chemical reactivity range (Pinova 2013). Table 2 shows the chemical properties of wood rosin.

Table 2: Chemical properties of wood rosin (Pinova 2013)

Property	
Form	Hot molten liquid or solid
Color	Dark red
Odor	Typical rosin (pine)
Softening Point/Boiling Point	79 C (>=174 F)/>300 C (>572 F)
Flash Point	188 C (370 F)
Solubility in Water	130 mg/L

As mentioned previously, wood rosin has grade designations established by the USDA.

Specific Uses of the Substance:
Wood rosin is used in organic processing and handling primarily as a component of fruit wax. Section 21 CFR 172.210(b) (2) stipulates that wood rosin (grade K) may be used as "coatings applied to fresh citrus fruit for protection of the fruit." Modified versions of wood rosin (e.g., glycerol esters of wood rosin) are otherwise used as ingredients in beverages containing citrus oils not to exceed 100 ppm in the final beverage (21 CFR 172.735). It may also be used in cosmetics such as mascara, lipsticks and eye shadow (DermNet NZ 2013).

Other uses of wood rosin are for industrial applications, such as soaps for cleaning, construction adhesives (walls, floors, etc.), as well as for other wax modifications in sealants and inks. (Pinova 2013).

Approved Legal Uses of the Substance:
Wood rosin is permitted as an ingredient in conventional citrus fruit waxes according to FDA regulations 21 CFR 172.210(b)(2) if it is color (grade) K or paler, and only if the minimum amount is used to obtain the desired effect. Section 21 CFR §73.1 permits rosin and rosin derivatives as diluents in color additives for conventional food use, such as marking food tablets, gums, and confectionaries, as well as in inks for marking fruit and vegetables. It is also permitted as an indirect food additive according to 21 CFR 178.3870. Specifically, rosins and rosin derivatives (as identified in 21 CFR 178.3870) may safely be used in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of the section (FDA 2013).

Although modified versions of wood rosin (e.g., glycerol esters of wood rosin) are not considered part of the scope of this Technical Report, it should be mentioned that a variety of modified versions are used as ingredients in beverages and as bases for chewing gum. The legal identity and uses of these modified versions may be found in 21 CFR §§ 172, 175, and 178.

Currently, wood rosin is erroneously listed as "wood resin" in section 205.605(a) of the USDA organic regulations. FDA regulations clearly permit and define only wood rosin as described in this report and do not define or permit wood resin as a direct or indirect food additive. Wood resin is the raw material produced by coniferous trees prior to distillation of any terpene, tall oil, and other components. EPA regulations also do not define wood resin or permit its direct use as an inert or active ingredient in pesticide formulations (EPA 2013).

Action of the Substance:
At the most basic level, wood rosin, when formulated as part of a fruit wax, reduces the gas exchange between the surface of the fruit and the atmosphere, which in turn reduces the respiration rate and resulting weight loss. 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 also 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. Wood rosin, when formulated with carnauba wax at differing percentages, only offers limited resistance to water vapor unless carnauba wax consists of approximately 90% of the formula (Hagenmaeier and Baker 1994). Fruit coatings made of wood rosin and shellac generally have lower permeability to CO_2 and O_2 and ethylene gases (Krochta, Baldwin and Nisperos-Carriedo 1994).

Another reason for using wood rosin-based fruit waxes is to add a sheen or shiny appearance to the fruit. For example, wood rosin and shellac are thought to offer the most shine but can cause low O_2 and excessive build-up of CO_2, leading to fermentation and off-flavors, among other disorders (Krochta, Baldwin and Nisperos-Carriedo 1994). Studies have shown that fruit coatings also reduce decay incidence and suppress degreening, chilling injury, and pitting (Sharma, et al. 1989, Davis and Harding 1960).

Combinations of the Substance:

Raw wood rosin is sold directly to further formulators of fruit wax and other products without any additional ingredients such as stabilizers or preservatives (Pinova 2013).

Wood rosin, when used as an ingredient in a citrus fruit wax, appears to always be formulated with additional ingredients in order to create characteristics that are favorable to commercial fruit wax formulations. Hagenmaier and Baker (1994) studied the effects of several different fruit waxes, noting the formula for the wood resin [rosin]-based wax as follows: 9.3% wood resin [rosin], 9.4% shellac, 1.3% oleic acid, and 4.7% morpholine. Krochta, Baldwin and Nisperos-Carriedo (1994) write that 'natural' coatings may contain "wood rosin, shellac, coumarone indene resin, emulsifiers, plasticizers, anti-foam agents, surfactants, and preservatives." Krochta, et al. (2004) states that wax used on citrus is composed "primarily of water, shellac, and/or wood rosin with a small amount of morpholine (to raise pH in order to solubilize shellac), oleic acid, and frequently oxidized polyethylene." Plotto and Narcisco (2006) note that anti-foamers such as polydimethylsiloxane or silicon dioxide may also be added (although may not be necessary). Further, the addition of fungicides and insecticides in wax formulas is also common to prevent decay during storage and transport (Davis and Harding 1960). It is not known whether there are wood rosin based fruit waxes that are combined with substances from the National List available in the market. OMRI does not currently have any fruit wax products listed containing wood rosin (OMRI 2013). A patent for Natural Technology International Limited (Fu, et al. 2013) provides a myriad of possible combinations proposed for wood rosin-based fruit waxes on organically* produced fruits and vegetables. The following table summarizes the possible combinations covered by the patent:

Table 3: 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	Nicotinic 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

* Ingredients listed in this patent may or may not be compliant for use on organically produced fruits according to 7 CFR Part 205.

Status

Historic Use:

Wood rosin was reviewed and voted for listing on the National List by the NOSB in 1996 under the general term "fruit waxes." The original Technical Advisory Panel Report (TAP) called it "wood resin" and it is currently listed as such on 205.605(a) (NOP 1996). Historical use of wood rosin in organic food processing appears to be limited to its use as a component of tree fruit waxes, primarily for citrus.

The practice of coating fruits to prevent moisture loss and create a shiny surface has been used for centuries. For example, as early as the 12th century, citrus fruits from South China were prepared for the emperor's table by placing them in boxes and pouring molten wax over them. Prior to 1967, edible films were limited to waxes used to coat fruits (Pavlath and Orts 2009).

Organic Foods Production Act, USDA Final Rule:

Wood rosin 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]).

International

Of the four most prevalent organic standards (U.S., EU, Canada, JAS), wood rosin [resin] is currently only permitted under the U.S. organic regulations and the Canada Organic Standards.

Canada - Canadian General Standards Board Permitted Substances List –
Wood rosin 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) - ftp://ftp.fao.org/docrep/fao/005/Y2772e/Y2772e.pdf
Wood rosin is not permitted as a food additive under the Codex Alimentarius. It does not appear in the CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling, and Marketing of Organically Produced Food.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Wood rosin is not permitted in the European Union as a food additive in organic processed foods. It does not appear in EN 2092/2007 Annex VI Section A – Ingredients of Non-Agricultural Origin.

Japan Agricultural Standard (JAS) for Organic Production
Wood rosin is not permitted in Japan as a food additive in organic processed foods. It does not appear in the Japanese Agricultural Standard for Organic Processed Foods (Notification No. 1606, 2007), Table 1: Food Additives.

International Federation of Organic Agriculture Movements (IFOAM) –
Wood rosin is not permitted by the IFOAM Standard as a food additive in organic processed foods. It does not appear in Appendix 4 – Table 1: List of Approved Additives and Processing/Post-Harvest Handling Aids.

Evaluation Questions for Substances to be used in Organic Handling

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

Highly resinous Longleaf and Slash pine stump wood is ground into small chips and loaded into vertical, cylindrical extractors. The resinous material is extracted using a ketone solvent. Although the specific ketone solvent used by Pinova Solutions, Inc. is proprietary (Merck 2013), Beglinger (1958) indicates that a petroleum or coal-tar solvent such as benzene is used. However, benzene is not a ketone, so Pinova's solvent may also be acetone, methyl ethyl ketone, methyl isobutyl ketone and/or di-isobutyl ketone. The EPA's Toxic Release Inventory (TRI) regulates Pinova Inc. as a TRI facility (ID # 31520HRCLS2801C) that may release methyl isobutyl ketone (MIBK) (EPA 2013). For the purposes of question 9 below, this substance will be analyzed in the absence of confirmation of the specific ketone used by Pinova, Inc. Wood chips are passed through a series of extractors where each batch of new chips is extracted with several portions of solvent in succession. Each portion of solvent is used on several different batches of chips. This is a counter-current process where fresh solvent is used on the final extraction of the wood chips, and then it is successively used on the chips that receive one, two or three more extractions. Thus, the oldest solvent is used on the freshest wood chips. After the wood chips have received the final solvent extraction wash, the solvent is drained and the chips are pressure-steamed to recover any residual solvent. The solvent from the terpene oil-rosin solutions leaving the extractors is recovered by vacuum-distillation seperation and reused for subsequent extraction processes. Merck (2013) indicates that all of the ketone solvent is reused and none is disposed (beyond point source emissions permitted by EPA regulations). The resulting terpene oils are separated by fractional distillation into refined terpentine, dipentene, and pine oil. The remaining residue is the non-volatile extract and is considered to be crude wood rosin (not food grade). The crude wood rosin is further refined and purified by a liquid fractionation process. It is placed into refining towers where a proprietary polar solvent (Merck 2013) is used to extract the darker components. According to the EPA Toxic Release Inventory (2013), methanol is the likely solvent used in this process step. The solvent is evaporated off, recovered and reused. The resulting lighter wood rosin is called Vinsol and the remaining, darker grade (Grade K) wood rosin is that which is considered 'food grade' and permitted as an ingredient in citrus fruit waxes (Merck 2013). The manufacturing process may only differ by the solvents used, but this is the only known method for manufacturing wood rosin. No chemical changes occur during the extraction and refinement of wood rosin.

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

Wood rosin is derived from and is considered a by-product of the pulp and timber industries. Although pine trees are plants and wood rosin is used for human consumption, the trees are primarily grown for timber and paper purposes and thus wood rosin does not meet the definition of "agricultural product" as defined by §205.2.

As described earlier, wood rosin is primarily chemically extracted from Slash and Longleaf pine stumps through a counter-current process and further refined through fractional distillation. Solvents such as MIBK are typically liquids that dissolve another substance, resulting in a solution. Solvents are selected by the specific chemical properties that enable the solute (e.g., wood resin) to dissolve. A solution consists of all ingredients uniformly distributed at a molecular level (Ashenhurst 2013). Thus, when wood chips are placed into MIBK or other ketone solvent, the wood resin dissolves into the solvent. The solvent is then removed from the terpene oil-rosin solution by vacuum distillation, leaving the terpene-oil rosin solution. This solution of terpene-oil rosin is then fractionally distilled to yield further products, and the non-volatile portion is wood rosin.

Fractional distillation is a physical process that separates components of a solution based on their boiling points or volatility. Fractional distillation is distinguished from simple distillation in that a liquid is successively re-distilled automatically in a fractionating column. As the terpene-oil rosin solution is boiled, it turns to vapor and rises up the column. This purification method is dependent on the differences in boiling points of each compound. The compound with the lowest boiling point will rise farther up the column while condensing to a liquid and evaporate to a gas than compounds with lower boiling points. Over time, the degree of separation increases significantly and combined with redistillations results in compounds being separated with high purity. (Mohrig and Schatz 2006). This will continue until all the remaining vapor rises, hits the condenser and is collected as a liquid. The substance that remains is the non-volatile residue, or crude wood rosin. The crude wood rosin is subsequently placed into refinement towers with a polar solvent. This is another chemical extraction process similar to the initial extraction of the terpene-oils solution from the wood chips.

Although the extraction process is chemical, there are no chemical changes occurring in the various components of the terpene-oil rosin solution. Neither does the wood rosin undergo chemical changes during the fractional distillation and subsequent further chemical refinement steps. At both stages of extraction, the solvent is removed by vacuum-distillation, another physical process.

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)).

Wood rosin is currently classified as nonsynthetic and appears at section 205.605(a) as a nonsynthetic wax permitted as an ingredient in or on organic processed foods. While wood resin is the wholly unprocessed substance from which wood rosin is derived, wood resin does not function as a substitute for wood rosin in its primary use as a fruit wax. Further, wood resin is not permitted as a food additive by the FDA (FDA 2013).

<u>Evaluation Question #4:</u> 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.

Wood rosin is not categorized as GRAS by the FDA regulation or by the FDA GRAS Notice Inventory. However, wood rosin is permitted as an ingredient in citrus fruit waxes according to FDA regulations at 21 CFR 172.210(b)(2) if it is color (grade) K or paler, and only if used in the minimum required to accomplish the desired effect. It is also permitted as an indirect food additive according to 21 CFR 178.3870. Specifically, rosins and rosin derivatives (as identified in this section) may safely be used in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of the section (FDA 2013) .

<u>Evaluation Question #5:</u> 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). Wood rosin is primarily used as an ingredient in fruit waxes applied to citrus. The primary function of wood rosin fruit waxes 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. Bayindirli, Sumnu and Kamadan (1995) found that two fruit coatings (SemperFresh™ and JonFresh™) delayed the ripening of mandarins. 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. However, there is noliterature specifying that wood rosin-based fruit waxes specifically help to prevent decay and/or act as a preservative.

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

One of the characteristics that wood rosin fruit waxes impart is sheen to the fruit surface (Krochta, Baldwin and Nisperos-Carriedo 1994). 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, and applying a commercial fruit wax would replace the 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, wood rosin fruit waxes 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). For example, Hagenmaier and Shaw (2002) note that concentrations of ethanol, ethyl acetate, ehtyl butyrate, isopentanol and 2-methyl-3-buten-2-ol in tangerines increased during storage on fruits coated with high-gloss, shellac and wood rosin waxes, leading to significant flavor deterioration.

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 wood rosin based fruit waxes have any particular effect on nutritional quality. 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 with edible rinds or peels. (Krochta, Baldwin and Nisperos-Carriedo 1994). Since wood rosin based fruit waxes are primarily applied to citrus fruits, where the rind is peeled and discarded, the potential nutrient fortification of such coatings is not applicable.

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)).

According to Pine Chemicals Association, Inc. (2004), wood rosin does not contain substances or residues that exceed FDA's Action Levels for Poisonous or Deleterious Substances in Human Food. A review of several specification sheets and MSDS's for wood rosin also confirmed that residues for heavy metals or other contaminations are not reported (Pinova 2013). The European Chemicals Bureau's review of wood rosin confirms that impurities either do not exist, or are not of concern to note in the report (European Chemicals Bureau 2000).

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)).

There are three areas where the manufacture, use, and breakdown products may affect the biological, chemical and physical environment or biodiversity. First, since wood rosin is derived from pine wood, some environmental effects result from their harvest. The solvent extraction of wood rosin is also an important part of the manufacture that has potential effects on the environment. Finally, wood rosin has been studied for its toxicity in the aquatic and biological ecosystems.

Wood rosin is derived primarily from two pine species – Slash pine and Longleaf pine. According to the IUCN Red List of Threatened Species (2013), Slash pine is categorized as a species of "least concern" on the continuum of threatened species. On the other hand, Longleaf pine is categorized as "endangered." Both species are harvested primarily for timber and pulp products, while wood rosin is considered a by-product of the timber industry since it is derived from the remaining stumps of these trees. Longleaf pine was one of the most common pines in the Coastal Plains. Timber exploitation and conversion to farmland reduced the hectares from 25 million to less than 5 million in 2000. Further, replanting of the species is not favored and so many sites that might have been dominated by Longleaf pine are now planted in other species. Longleaf pine grows slowly and thus cannot economically compete with other pine species for replanting and establishment (Landers, Van Lear and Boyer 1995). Slash pine does not have any significant threats to its continued healthy population (Farjon 2013).

The solvent extraction of wood rosin from the wood chips is another potential source of environmental effects. Although the specific solvents used by Pinova, Inc. are proprietary, the EPA Toxic Release Inventory (2013) suggests that methyl isobutyl ketone (MIBK) is the likely solvent used for the initial extraction, and methanol for the further refinement. MIBK is identified by the FDA as a synthetic flavoring substance and adjuvant (Section 172.515) and has been the subject of a toxicological review by the EPA (2003). According to the EPA (2003), human studies of acute inhalation exposures to MIBK indicated "transient sensory irritation, neurological effects, and/or strong odor sensation during exposure". Another study showed some nose and throat irritation at an exposure rate of 100-200 mg/m3. A study by the National Institute for Occupational Safety and Health on the other hand did not find any changes in neurological or irritation systems after a 2-hour exposure to MIBK at 100ppm (EPA 2003). The NOAEL and

LOAEL[1] for male and female rates was 1000 mg/kg/day and undetermined, respectively. At 1000 mg/kg/day, rats had increased obsolete and relative liver, kidney, and adrenal weights (EPA, 2003). The EPA TRI (2013) indicates that from 2008 through 2012, Pinova, Inc. released 2, 787,000 lbs of MIBK through on-site air emissions. As mentioned previously, Merck (2013) indicates that all solvents are recovered after the extraction and refinement of wood rosin, except for emissions permitted by the EPA. Pine Chemicals Association, Inc. (2004) indcates that "air emissions generated from…[the solvents], are generally collected and treated in chemical scrubbers or thermal oxidizers" (page 29). For the second extraction step, methanol is considered to be environmentally preferable to other solvents of similar properties (Capello, Fischer and Hungerbuhler 2007). However, workers repeatedly exposed to methanol have experienced headaches, sleep disorders, gastrointestinal problems and optic nerve damage. Exposure to large amounts of methanol can result in death or severe abdominal, leg and back pain (EPA 1994). No information is available on the carginogenic, reproductive, and developmental effects of methanol in humans, but birth defects have been observed in the offspring of rats and mice exposed to methanol by inhalation (EPA 2000)

Finally, wood rosin itself has some environmental effects to consider. Because of its low water solubility and lack of any vapor pressure, wood rosin will likely not enter the atmosphere. It biodegrades by 32% at 28 days and is nearly completely resistance to hydrolysis in the presence of water (Pine Chemicals Association, Inc. 2004; European Chemicals Bureau 2000). Ecotoxicity data for wood rosin indicate that it is non-toxic to fish, daphnia, and algae. Table 4 summarizes the ecotoxicity data for aquatic life.

Table 4: Ecotoxicity data for wood rosin in aquatic life (Pine Chemicals Association, Inc. 2004)

Chemical	Fish 95 hour *$NOEL_r$	Daphnia 48 hour $NOEL_r$	Algae 72 hour $NOEL_r$
Rosin	100 mg/l	750 mg/l	1000 mg/l
*$NOEL_r$[2] – No Observed Effect Loading Rate			

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

There are two areas where exposure to wood rosin and its derivatives may affect human health: as a dermatological irritant (allergy), and asthma. Both symptoms occur primarily after occupational exposure to wood rosin or the products it occurs in (adhesives, soldering flux, etc.).

Contact with rosins has been reported frequently as a cause of dermatitis in patients. Exposure to an irritant such as wood rosin that results in inflamed skin is diagnosed as "contact dermatitis" (DermNet NZ 2013). It is now included in a standard series of test patches to diagnose dermatitis. In Germany, the results of patch tests with rosin (referred to as colophony) between 1983 and 1987 were analyzed. Of 5,875 patients, three percent, or 175 tested positive for allergy to rosins. A similar investigation in Sweden revealed a rate of 3.4% positive reaction to rosin. Subsequently, rosin was ranked number 4 on the list of most common causes of positive patch test reactions in Sweden (European Chemicals Bureau 2000). Development of sensitivity to wood rosin depends on length of exposure, the concentration of the allergen, exposure sites, skin integrity, and the variable chemical constituents of the particular rosin. It should be noted, however, that of the sources and occupations most reported for risk of exposure, the manufacture or consumption of fruit wax is not one of them (Downs and Sansom 1999). A review of the literature shows no direct reference to dermatitis caused by consuming or using wood rosin based fruit waxes.

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[1] NOAEL – no observed adverse effect level; LOAEL – lowest observed adverse effect level

[2] No Observed Effect Loading Rate is also known as the 'no observed adverse effect level' (NOAEL). The EPA defines it as "an exposure level at which there is no statistically or biologically significant increases in the frequency or severity of adverse effects between the exposed population and its appropriate control; some effects may be produced at this level, but they are not considered as adverse, or as precursors to adverse effects. In an experiment with several NOAELs, the regulatory focus is primarily on the highest one, leading to the common usage of the term NOAEL as the highest exposure without adverse effects" (EPA n.d.).

Rosins have also been documented as a source of occupational asthma, especially in the electronics industry where they form part of the soldering flux. Workers exposed to fumes generated when the rosin is heated are particularly at risk (Cullen, Cherrie and Soutar 1992), where the disease rate for bronchial asthma is between 4% and 20% (Keira, et al. 1997). The mode of action through which rosin causes bronchial asthma is via initial inhalation of the fumes. Responsiveness increases markedly 3 hours after the exposure, followed by development of delayed asthma. Thus, it is shown that the asthma is induced by an increase in bronchial responsiveness, such as an inflammatory methanism (Keira, et al. 1997). It was primarily thought that heating the rosin to very high temperatures causes it to decompose, and these breakdown products are what cause the asthma. However, Burge et al. (1986) reported a case of asthmatic reaction in a worker that had been exposed to solid rosin at room temperature. Asthmatic symptoms have also been reported in feather plucking workers, where rosin is used in the plucking process. Ayars, et al. (1989) found that exposure to abietic acid (a major component of wood rosin) can injure epithelium of alveoli, trachea, and bronchi, promoting pulmonary disorder. Currently, the United Kingdom considers asthma arising from exposure in industrial settings to be a disease eligible for industrial injuries compensation (Cullen, Cherrie and Soutar 1992).

Wood rosin has been studied for acute oral[3] and repeat dose toxicity[4], as well as for genotoxicity in bacteria and mammalian cells, and effects on reproduction and development. Following is a summary of the results of these tests.

Table 5: Summary of Human Health and Toxicity Parameters of wood rosin (adapted from Pine Chemicals Association, Inc. (2004))

Acute Oral LD_{50}	**Repeat Dose NOEL**	**Genetox (bacteria)**	**Genetox (Mammal)**	**Reproduction/Development**
>5000 mg/kg	105-200 mg/kg/day	No tumors in 2 yr. cancer bioassay	No tumors in 2 yr. cancer bioassay	275 mg/kg/day

Adequate data for acute toxicity, repeat dose toxicity, and reproductive effects indicate that these compounds are non-toxic. Additionally, the available two-year feeding studies on wood rosin showed a lack of carcinogenicity. The EPA (2005) concluded that based on the toxicological information available on similar chemical structures, there is low to moderate human health concerns due to potential dermal and respiratory sensitization. However, absorption by all exposure routes is very poor.

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

[3] Acute oral toxicity studies measure the effect(s) of a single exposure to a relatively high dose of a substance. The test is conducted to obtain information on the biological activity of a chemical. The LD_{50} value, defined as the statistically derived dose that is expected to cause death in 50% of the treated animals in a given study is the current classification of chemicals. Typically, mice and rates are the species used for testing (Walum 1998).

[4] Repeated dose toxicity testing uses oral or inhalation administration of a substance in rodents for 28 and 90 days to evaluate chronic toxic affects, primarily on organ systems and to establish a 'no observed effect level' (NOEL). Doses are selected to be sublethal but still cause toxic effects (AltTox.org 2007).

water loss. Therefore, handlers can reduce water loss by monitoring and controlling the atmospheric conditions as much as possible during storage and transport. However, this practice should take into account the different varieties and their susceptibility to chilling injuries and other storage issues (Reuther, Calavan and Carman 1989).

Although the literature does not agree on how effective wood rosin fruit waxes are in preventing decay, they have been shown to prevent likely disease vectors from coming into contact with the fruit surface by forming a physical barrier. Some alternatives to using waxes as a prevention mechanism include the use of hot water sprays, and sodium carbonate and bicarbonate applications (Palou, et al. 2001). However, it should be noted that these applications were more effective in preventing decay in short-term storage and less so in long-term cold storage. Porat, et al. (2000) found that a hot water brushing treatment in organic citrus fruit reduced decay development by 45-55% in certain citrus cultivars, and the treatment at 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. It should be noted that the literature does not suggest that these alternative practices make fruit waxes completely unnecessary.

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)).

There are primarily four different nonsynthetic substances that may be used in place of wood rosin as a component of citrus fruit waxes: Orange shellac, carnauba wax, beeswax, and candelilla wax. Each has their own positives and negatives for various factors, including shine, permeability, cost, etc. Of these four, only orange shellac and carnauba wax are permitted as nonorganic ingredients in fruit waxes used on organic fruit. Otherwise, organic beeswax and organic candelilla wax would be required for use on organic citrus fruits. See question 13 below for more complete information on beeswax. Figure 2 demonstrates that different types of fruit coatings affect internal gas and ethanol concentrations in four apple cultivars.

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, and chitosan. (Hagenmaier 1998; Krochta, Baldwin and Nisperos-Carriedo 1994; Bai, et al. 2003; Park 1999). However, none of this literature suggests that these are suitable as complete replacements for wood rosin.

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

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 in addition to citrus. Commercial waxes containing shellac are used to coat pears, apples mango, papaya, and avocado (Hagenmaier and Shaw 1992),. It is also used as an ingredient in candy coatings and pharmaceutical casings. Like wood rosin, shellac is considered a resin and so permeability is very low and moderately resistant to water vapor. In general, shellac coatings dry faster, coat better, and produce a better 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 wood rosin depends also on the availablility of other substances for further formulation in edible coatings.

Carnauba wax

Carnauba wax is reported to have low oxygen and moisture permeability, though it is more permeable to O_2 and CO_2 than wood rosin and shellac (Hagenmaier and Shaw1992). The gas barrier also impedes oxidation of oils which in turn reduces rancidification of fatty foods such as nuts (Mayhar et al., 2012). Maintaining internal oxygen levels of fruit with dilute concentration of carnauba wax coating can also maintain flavor (Jacomino et al., 2003; Hagenmaier and Shaw 1992). Hagenmaeier and Baker (1994) found that oranges coated with carnauba wax-based fruit coatings had less weight loss, lower internal CO_2, higher internal O_2, and better water resistance than those coated with wood rosin or shellac. Used as a fruit coating, carnauba wax acts as it does on the plant on which it originates: it reflects light giving the fruit a shiny appearance, reduces loss of moisture and mass, prevents fungal attack, and postpones decay. Carnauba wax prevention of fungal attack in post-harvest fruit can also be attributed to antifungal properties beyond just creating a gas barrier. One study in which proteins were isolated from the various fractions of carnauba wax found antifungal enzymatic activity of the proteins. These enzymes, chitinase and β-1,3-glucanases, can inhibit early growth of fungi and alter hyphal (threadlike filaments forming the mycelium of fungi) morphology of fungi growing in the presence of the proteins (Cruz et al. 2002). Carnauba wax is also available in organic forms, as opposed to wood rosin and orange shellac, and is formulated in products compliant for use as fruit waxes on organic foods (OMRI 2013). The 2012 list of certified USDA organic operations (NOP 2012) lists seven operations in Germany, Brazil, and the U.S. that produce or handle organic carnauba wax. It should be noted however that the literature suggests that carnauba wax is often formulated with other waxes such as shellac, wood rosin, beeswax, and candelilla in order to produce the most advantageous characteristics (Dou, Ismail and Petracek 1999, Hagenmaier and Shaw 2002, Lin and Zhao 2007). Therefore, its use as an alternative to wood rosin primarily depends also on the availablility of other substances for further formulation in edible coatings.

Candelilla wax

Candelilla wax is obtained from the desert plant *Euphorbia antisyphilitica,* and is extracted from the leaves with boiling water (Hagenmaier and Baker 1996). It is a hard wax that has been studied extensively as a component of fruit coatings, especially for citrus (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 candelilla wax provided an "attractive gloss" to the fruits, did not alter the chemical composition of limes, and had differing affects on color retention of the peel. For example, a mesquite gum-candelilla wax-mineral oil emulsion applied to the limes prevented the most weight loss and had the highest gloss, providing the fruit with a fresher appearance than candelilla wax alone. Candelilla wax[5] is also used to improve the shelf life and quality of avocado by minimizing the changes in appearance, solids content, pH, and weight loss. Candelilla wax has the lowest permeability to water vapor of any lipids (Krochta, Baldwin and Nisperos-Carriedo 1994). However, it should be noted that the literature suggests that candelilla wax based fruit coatings are often formulated with other components such as carnuaba wax, wood rosin, shellac, beeswax, vegetable oil, ammonium, and morpholine (Krochta, Baldwin and Nisperos-Carriedo 1994; Hagenmaier and Baker 1996). Thus, it should not be considered to be a complete replacement for wood rosin without the availability of other compliant components. There are no certified organic sources of candelilla wax at this time (National Organic Program 2012).

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

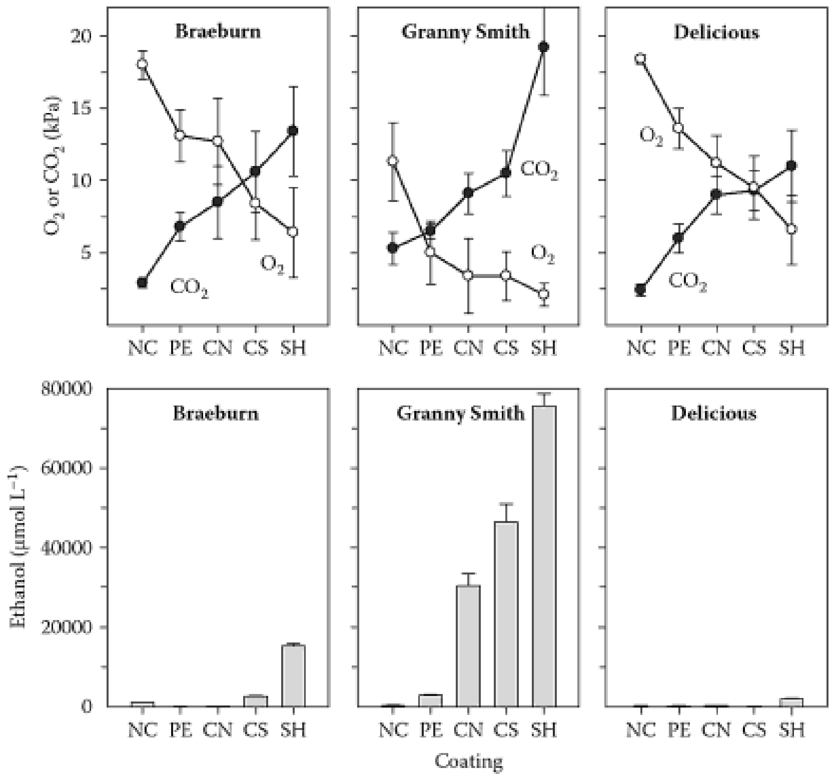

Figure 2: Internal gases (top) and ethanol concentrations (bottom) of three apple cultivars after 5 months of room temperature storage then coated and stored at 20° C for two weeks. (NC – No Coating; PE – Polyethylene, CN – Candelilla; CS- Carnauba – shellac; SH – shellac). (Krochta, Baldwin and Nisperos-Carriedo 1994)

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

Pinova Solutions, the sole manufacturer of wood rosin, does not offer certified organic wood rosin (Merck 2013). Therefore, a certified organic wood rosin fruit wax is not available on the market as an alternative to nonorganic wood rosin fruit waxes. Of the alternatives discussed in Question 12 above, only carnauba wax and beeswax are available in organic form (NOP 2012). See Question 12 for more information about organic carnauba wax as an alternative to wood rosin.

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 and has been found to have anti-browning effects on cut fruit[6] (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

[6] Perez-Gago, et al. (2003) compared different formulas of beeswax and whey protein isolate to determine the weight loss and color changes in cut fruit. 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.

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 wood rosin 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).

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