Glycerin

Handling/Processing

Identification of Petitioned Substance

Chemical Names: Glycerin

Other Name: Glycerin, Glycerine, 1,2,3-Propanetriol, Glyceritol, Glycyl alcohol, Trihydroxypropane, Propanetriol, Osmoglyn, 1,2,3-trihydroxypropane

Trade Names: Citifluor AF 2; Glycerin mist; Glyceritol; Clyzerin, wasserfrei (German); Grocolene; Moon; Osmoglyn; Star; Optim; Glyrol, Bulbold, Superol, Dagalaxx, Glysanin

CAS Number: 56-81-5

Other Numbers:
CID: 753
INS Number: 422
CB Number: CB5339206
InChIKey: PEDCQBHIVMGVHV-UHFFFAOYSA-N

Summary of Petitioned Use

Glycerin—produced by hydrolysis of fats and oils was added to section 205.605(b) of the USDA Organic Program's (NOP) National List as a synthetic nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." Glycerin has a wide variety of uses in many organic products as a humectant, a solvent, an emollient, a sweetener, a bodying agent, a preservative, filler in low fat foods, an alcohol free solvent for botanical extracts, cosmetics and pharmaceutical agents, a thickening agent in liqueurs, a hydrating agent used in sports and energy drinks and in the manufacture of cellophane, cosmetics and meat casings. The petition proposes to remove glycerin from section 7 CFR 205.605 of the National List. The petitioners assert that glycerin produced from organic starting materials using processing methods satisfying the Organic Food Production Act of 1990 is now available in sufficient quantities to meet commercial needs. The petitioners represent glycerin manufacturers that use an alternative method to hydrolysis, but hope to incentivize the purchase of all organic glycerin products.

Characterization of Petitioned Substance

Composition of the Substance:
Glycerin is a trihydroxy sugar alcohol. It is the simplest trihydric alcohol and considered a derivative of propane. Glycerin is classified as a nonagricultural substance in section 205.605; however, certified organic glycerin derived from agricultural products is available. Practically, organic glycerin is extracted from a fraction of a processed organic agricultural product. Whereas, the identity of the initial agricultural product i.e. fats, oils or starch is unrecognizable in both fraction and extract.

Source or Origin of the Substance:
Carl Wilhelm Scheele, a German chemist, first discovered and isolated glycerin in 1778, while working on the saponification of olive oil with lead oxide. In 1813, Michel Eugene Chevreul, a French lipid chemist, showed that fats are glycerin esters of fatty acids. He also gave glycerin its name, "γλυκεροληζ", the Greek word for sweet. Pasteur, in 1857, showed alcoholic fermentation of sugars produced glycerin and succinic acid. Glycerin is an intermediate in cellular carbohydrate and lipid metabolism found naturally in all living organisms.

Glyceride esters of the higher fatty acids found universally in all living matter, both animal and vegetable, are a basic type of food and important to industry. The natural fats are triglycerides, with minor amounts of other substances, and with few exceptions are straight chain compounds with an even number of carbon atoms. Fatty acids may be saturated, unsaturated, and/or hydroxylated. The possible number of glycerides is great and the number described in the literature is large. There are two processes leading to production of glycerin for the National List: steam heating and saponification with alkaline chemicals. Both produce glycerin by hydrolytically splitting fats and oils into two readily isolated molecular fractions: fatty acids and glycerin. Organic glycerin is also manufactured by microbiologically fermenting organically produced sugar or starch followed by concentration and purification.

Glycerin has long been an industrially useful by-product of the soap, candle, and biodiesel industries. Although glycerin is also produced from biodiesel and petroleum products by other synthetic processes, only non-organic glycerin meeting the requirements specified by 7 CFR 205.605 is permitted in USDA organic products.

Properties of the Substance:

Glycerin has the chemical formula, $C_3H_8O_3$. Its molecular weight is 92.09. Glycerin is a clear, colorless syrupy liquid that forms solid rhombic crystals below its melting point of 18^{o}C. The boiling point of glycerin is 290^{o}C. The specific gravity and refractive index of pure glycerin at 20^{o}C, respectively is ≥1.249 g/ml and ≈1.4746. A two dimensional structural representation of glycerin is provided in Figure 1.

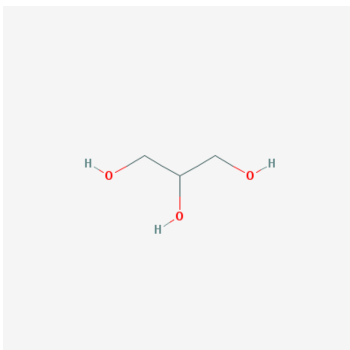


Fig. 1 Two-dimensional Chemical Structure of Glycerin

Glycerin is described as having a mild odor and a sweet warm taste (about 0.6 times that of cane sugar). It has a neutral pH. Glycerin is soluble in water and ethanol, slightly soluble in ethyl ether and insoluble in benzene, carbon tetrachloride, chloroform, carbon disulfide, and petroleum ether.

Specific Uses of the Substance:

Glycerin quality ranging from crude, soap lye glycerin to a highly purified product determines its specific use. According to the US Pharmacopeial Convention, USP glycerin, the minimum quality for food grade glycerin must conform to the minimum criteria presented in Table 1.

Approved Legal Uses of the Substance:

According to Title 21 CFR 182.1320 of the federal register, glycerin is a multiple purpose generally recognized as safe (GRAS) food substance when used according to good manufacturing practice. According to Title 40 CFR 180.950 of the federal register, glycerin is exempt from a tolerance by the US Environmental Protection Agency, i.e. it may be used at any concentration in EPA regulated material. However, glycerin produced as a biodiesel by-product has occasionally been implicated in EPA violations involving dumping excessive amounts of glycerin into the environment. Details of any incident involving the production organic glycerin were not found.

Action of the Substance:

Glycerin reduces hydrogen bonding of water; specifically it reduces the bonding ability of the oxygen atom of water resulting in actions that include reducing water activity, increasing boiling point, and reducing the heat of fusion of water, e.g. preventing the formation of ice crystals. Manifest in these properties are the multiple uses for glycerin in the production of food and cosmetics, e.g. solvent, humectant, cryopreservative, thickener, emollient, etc.

Combinations of the Substance:

Although there are direct uses for glycerin, it is most often used used in combination with foods, cosmetics, pharmaceuticals or other substances. Non-organic glycerin may comprise no more than 5% for products labeled as “organic.” In addition, the use of non-organic glycerin would mean that a product could not be labeled as “100% organic.”

Status

Historic Use:

Glycerin, a 1,2,3-propanetriol, is a simple alcohol with many uses in the cosmetic, paint, automotive, food, tobacco, pharmaceutical, pulp and paper, leather and textile industries. International glycerin production by microbial fermentation, chemical synthesis from petrochemicals or biodiesel and hydrolysis of fats and oils exceeds 1.1 million tons per year. During World War I, high purity glycerin was essential for the production of explosives and was commercially produced by fermentation. This type of production declined because newer methods for hydrolytic production from fats and oils and chemical synthesis from petrochemical or biodiesel feedstocks produced higher glycerin yields and lacked the difficulties associated with extracting and purifying glycerin from culture medium. In recent years, new developments have improved both methods and yeast strains (non-GMO) allowing substantial overproduction of organic glycerin by fermentation.

Table 1 Purity and Quality Criteria for US Pharmacopeial Glycerin

Description	Specification		
Composition	Glycerin contains not less than 99.0 percent and not more than 101.0 percent of $C_3H_8O_3$, calculated on the anhydrous basis.		
Color	Its color, when viewed downward against a white surface in a 50-mL color-comparison tube, is not darker than the color of a of water standard made by diluting 0.40 mL of ferric chloride CS with water to 50 mL and similarly viewed in a color-comparison tube of approximately the same diameter and color as that containing the Glycerin.		
Identification	method: liquid chromatography	Criteria: passes	The retention time of the glycerin peak in the chromatogram of the sample solution[1] corresponds to that obtained in the chromatogram of the standard solution[2].•
Ethylene glycol and diethylene glycol limit	method: liquid chromatography	≤ 0.050 mg/ml	If a peak at the retention times for the diethylene glycol or ethylene glycol is present in the sample solution[1], the peak response ratio relative to 2,2,2-trichloroethanol is not more than the peak response ratio for diethylene glycol or ethylene glycol relative to 2,2,2-trichloroethanol in the Standard solution[2]; not more than 0.10% each for diethylene glycol and ethylene glycol is found.
Specific gravity	≥ 1.249		
Residue on ignition	< 0.01%		
Water	≤ 5.0%		
Chloride	≤ 0.001%		
Sulfate	≤ 0.002%		
Heavy metals	< 5µg/g		
Chlorinated compounds	≤ 0.003%		
Fatty acids and esters	Not more than 1 mL of 0.5 N sodium hydroxide is consumed[3].		
Assay for Glycerin	Titration assay with sodium periodate providing amount of glycerin present in product		

[1] Sample solution: 50 mg per mL of glycerin, accurately weighed, and 0.10 mg per mL of 2,2,2-trichloroethanol, accurately weighed (internal standard) in methanol.

[2] Standard solution: 2.0 mg per mL of USP glycerin reference standard, 0.050 mg per mL of USP ethylene glycol reference standard, 0.050 mg per mL of USP diethylene glycol reference standard, and 0.10 mg per mL of 2,2,2- trichloroethanol (internal standard) in methanol.

[3] Mix 50 g of glycerin with 50 mL of freshly boiled water and 5 mL of 0.5 N sodium hydroxide VS, boil the mixture for 5 minutes, cool, add phenolphthalein TS, and titrate the excess alkali with 0.5 N hydrochloric acid VS. Perform a blank determination

Organic Foods Production Act, USDA Final Rule:

Glycerin—produced by hydrolysis of fats and oils, is listed in the Federal Register under 7 CFR 205.603 synthetic substances allowed for use in organic livestock production as a livestock teat dip and under 7 CFR 205.605 nonagricultural, nonorganic, synthetic substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

Glycerin—produced organically by fermentation is an agricultural product as defined in 7 CFR 205.2, since it is a processed product produced from an agricultural commodity, e.g. cornstarch. According to 7 CFR 205.105 (c), to be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," products must be produced and handled without the use of nonagricultural substances used in or on processed products, except as otherwise provided in 7 CFR 205.605.

Part 7 CFR 205.270(a) provides that mechanical or biological methods including but not limited to heating, drying, mixing, grinding, churning, separating, distilling, extracting, fermenting, preserving, dehydrating, freezing, chilling, or otherwise manufacturing may be used to process an organically produced agricultural product for the purpose of otherwise preparing the agricultural product for market, suggesting that glycerin may be manufactured from organically produced starting materials provided that a mechanical or biological method is used. The same section provides that nonagricultural substances allowed under 7 CFR 205.605 may be used (1) in or on a processed agricultural product intended to be sold, labeled, or represented as "organic," pursuant to 7 CFR 205.301(b), if not commercially available in organic form and (2) in or on a processed agricultural product intended to be sold, labeled, or represented as "made with organic (specified ingredients or food group(s))," pursuant to 7 CFR 205.301(c). Thus, both organically produced and non-organic glycerin produced by hydrolysis of fats and oils meet criteria for organic production and handling.

International

Canada - Canadian General Standards Board Permitted Substances List

The Canadian National Standards Board's Organic Production Systems Permitted Substance List (CAN/CGSB-32.311-2006) permits the use of glycerin—produced by hydrolysis of fats and oils in organic products as a non-organic food additive. Non-organic glycerin produced by fermentation is not included in this list. Non-organic glycerin—produced by both hydrolysis of fats and oils and fermentation of starch are considered non-synthetic substances.

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

The CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labeling, and Marketing of Organically Produced Foods (GL 32-1999) lists glycerin as an ingredient of non-agricultural origin in Annex 2, Table 3 permitted for use in organic products of plant origin. Codex limits glycerin in organic foods to use: as a carrier for plant extracts and uses in untreated fresh fruit, surface-treated fresh fruit; processed fruit; surface-treated fresh vegetables, seaweeds, nuts and seeds; dried vegetables, seaweeds, nuts and seeds; vegetables and seaweeds in vinegar, oil, brine, or soy sauce; canned or bottled (pasteurized) and retort pouch vegetables and seaweeds; vegetable, seaweed, and nut and seed purees and spreads (e.g., peanut butter); vegetable, seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables); fermented vegetable and seaweed products, excluding fermented soybean products and herbs, spices, seasonings, and condiments (e.g., seasoning for instant noodles). As such, the document requires that the labeling and claims of a processed agricultural crop should not contain any ingredient of non-agricultural origin not listed in Annex 2, Table 3. There are no listed uses for glycerin in foods of animal origin.

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

Article 27 (1) of European Economic Community Council Regulation 889/2008 provides that non-organic glycerin can be used as a substance in the preparation of processed organic food of vegetable origin with the exception of wine as a result of its listing in Appendix VIII of the same regulation. Furthermore, the use of non-organic glycerin is listed only for plant extracts.

Japan Agricultural Standard (JAS) for Organic Production

Non-organic glycerin or its use is not cited in the Japanese Agriculture Standard for Organic Plants, Notification No. 833, March 28, 2012. The Japanese Agricultural Standard for Organic Processed Foods, Notification No. 834, March 28, 2012 provides that processing methods utilize physical and biological functions, avoiding the use of chemically synthesized food additives and agents. Non-organic glycerin is not listed in any MAFF standard as a potential food additive or veterinary therapy.

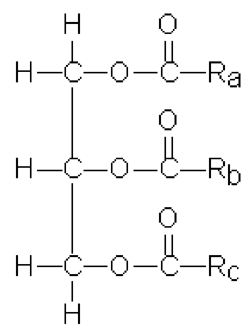
International Federation of Organic Agriculture Movements (IFOAM) –

IFOAM is consistent with both the Codex rule for the use of glycerin in food and EU Regulation 834/2008. A letter was sent by IFOAM to the head of the European Commission Organic Farming unit regarding a clarification as to the use of non-organic glycerin in food additives, because the use of non-organic glycerin was conditional. At the time of the preparation of this document, there is no indication that this situation was resolved.

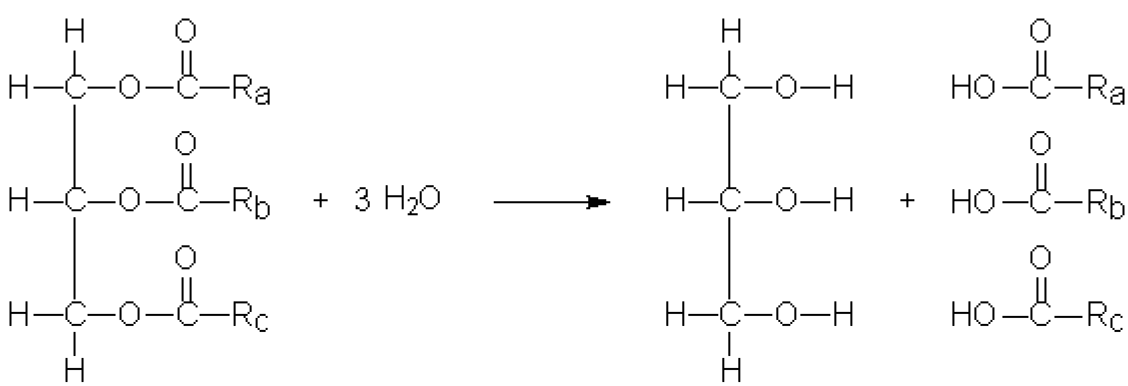
Evaluation Questions for Substances to be used in Organic Handling

<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)).

Fats and oils belong to a group of biological substances called lipids. Lipids are biological chemicals that do not dissolve in water. Fats differ from oils only in that they are solid at room temperature, while oils are liquid. Fats and oils share a common molecular structure.



This structural formula shows that fats and oils contain three ester functional groups: Ra, Rb and Rc. Fats and oils are esters of glycerin. Fats and oils are also called triglycerides. One of the reactions of triglycerides is hydrolysis of the ester groups:



Triglyceride **Glycerin** **Fatty Acids**

This hydrolysis reaction producing glycerin and fatty acids from triglycerides has been adapted for the manufacture of glycerin for organic use. The most common batch autoclave, hydrolysis methods are Lemmens and Fryer's Process, Budde and Robertson's process and Ittner's process. There is also a rapid process called continuous high-pressure hydrolysis that does not require a catalyst and takes approximately four hours (Table 2). Plants using these manufacturing processes have been operating since the 1930's. Recent improvements in plant engineering and filtration have resulted in better economy and purer product. Glycerin was considered a synthetic, because hydrolysis of fats and oils may require in addition to sodium hydroxide, calcium hydroxide, and potassium hydroxide that are on the National List, the use of catalysts such as zinc oxide, zinc hydroxide, or sulfuric acid that are not on the National List. Many of the fats and oils used and their potential yields are provided in Table 3. In addition, many of these can be organically sourced.

Glycerin is also a byproduct of soap and candle manufacturing. Crude glycerin products are recycled according to Twitchell's process, saponification, or Krebitz's process that provides for the removal of the sodium carbonate, sodium hydroxide or potassium hydroxide added to split the triglycerides in soap production. The final product resulting from these processes is often tinted or impure and requires distillation and filtration to achieve the purity necessary for food, cosmetic or pharmaceutical use. Other methods for glycerin production include synthesis from propylene and production of glycerin as a byproduct of biodiesel manufacturing.

Table 2 Processes for producing glycerin by hydrolysis of fats and oils

Lemmens Fryer's Process	Oil or fat is subjected in an autoclave to the conjoint action of heat and pressure (about 100 PSI) in the presence of an emulsifying and accelerating agent, e.g. zinc oxide or hydroxide (sodium hydroxide can be substituted) for about eight hours. The strong solution of glycerin formed is withdrawn and replaced by a quantity of hot, clean and preferably distilled water equal to about one third to one fourth of the weight of the original charge of oil or fat and treatment continued for an additional four hours. The dilute glycerin obtained from the latter part of the process is drawn off and used for the initial treatment of the further charge of oil or fat.
Budde and Robertson's Process	The oils or fats are heated and mechanically agitated with water and sulphuric acid gas, under pressure in a closed vessel or autoclave. The advantage claimed for the process are that the contents of the vessel are free from foreign matter introduced by reagents and need no purification; that the liberated glycerin is in the form of a pure and concentrated solution; that no permanent emulsion is formed and that the fatty acids are not discolored.
Ittner's Process	Coconut oil is kept in an autoclave in the presence of water at 70 atmospheres pressure and 225-245^{o}C temperature and split into fatty acids and glycerin, both being soluble under these conditions in water. The glycerin solution separates in the bottom of the autoclave. The aqueous solution contains at the end of the splitting process more than 30 percent glycerin.
Continuous High Pressure Hydrolysis	In this process a constant flow of fat is maintained flowing upward through an autoclave column tower against a downward counter-flow of water at a pressure of 600 PSI maintained at temperature of 480-495^{o}F. Under these conditions, the fat is almost completely miscible in water and the hydrolysis take place in a very short time. The liberated fatty acids, washed free of glycerin by the downward percolating water, leave the top of the column and pass through a flash tank while the liberated glycerin dissolves in the downward flow of water and is discharged from the bottom of the tower into the sweet-water storage tank.

Glycerin was commercially produced by fermentation of sugar and sugar containing products, e.g. molasses during World War I. However, the methods used at that time were inefficient and were eventually replaced by hydrolysis methods. More recently, osmotolerant yeast strains have been developed both through natural processes and genetic engineering for fermentation that can effectively maintain an industrial supply stream of glycerin. Organic glycerin manufacturing plants utilize process systems that are clean in place, usually with substances that are on the NOP National List, such as sodium hypochlorite. Organic glycerin is produced from organically produced raw materials, i.e. organic corn. Although, other grains or starch producing plant species may also be used: necessary is a source of carbohydrates. The grains are cleaned of debris, steeped in hot water; and subsequently coarse ground and centrifuged to enable the release and separation of the proteinaceous germ material and begin the starch solubilization process. Additional grinding and centrifugation allows the separation of gluten from the starch. Enzymes (Amylase, Glucoamylase, glucose oxidase) are added to the starch solution to convert the starch to dextrins and subsequently to monosaccharides, e.g. glucose.

Table 3 Glycerin and fatty acid content of various fats and oils

Name of oil or fat	Pure glycerin content of absolutely neutral oil	Total fatty acid content	Average content of free fatty acid in commercial oil	Pure glycerin content in commercial oil	Yield of pure glycerin, 28°Be, in commercial oil
	per cent glycerin				
Cotton seed oil	10.6	95-96	trace	10.6	12.05
Peanut oil	10.4	95.8	5-20	8.3-9.9	9.43-11.25
Flaxseed oil	10.4	95	1-2	10.3-10.4	11.70-11.82
Coconut oil	13.6	94-94.6	3-5	13.2-13.5	15-15.34
Coconut oil (off)	-------	94-94.8	15-40	9.3-11.8	9.43-13.41
Bone grease	10.5	95	20-50	5.2-8.4	5.91-9.55
Linseed oil	10.5	95.5	1-2	10.4-10.5	11.82-11.93
Corn oil	10.4	94-96	1-10	9.3-10.3	10.57-11.70
Olive oil	10.3	95	2-25	7.7-10.2	8.75-11.59
Palm kernel oil	13.3	94-94.6	4-8	12.2-12.8	13.87-14.55
Palm oil	11.0	95	10-50	5.5-10.0	6.25-11.37
Horse grease	10.6	95-96	1-3	10.5-10.6	11.93-12.05
Castor oil	9.8	94.5-95	6.5-10	8.8-9.8	10-11.14
Beef tallow	10.3	95.6	5	10.2	11.59
Rapeseed oil	9.7	95	1.7	9-9.7	10.23-11.02
Sesame oil	10.3	95.5	5-15	8.7-9.8	9.89-11.14
Soybean oil	10.4	95.5	2	10.2	11.59
Sunflower seed oil	10.4	95	1-5	9.9-10.3	11.25-11.70
Sulphur oil (extracted from olive press cake)	-------	95	30-60	4.7	4.55-7.95
Hog's grease	10.6	94-96	0.5-1	10.5-10.6	11.93-12.05
Vegetable tallow	10.9	94-95	1-3	10.5-10.8	11.93-12.28
Blubber oils	10.0	94-95.5	2-20	8-9.8	9.09-11.14
Train	10.0	94-95.5	2-20	8-9.8	0.09-11.14

After digestion of the starch is completed, the resulting syrup is sterilized with steam. Additional nutrients maybe added to support yeast growth in the next step. The sterile syrup is inoculated with a carefully selected glycerin producing yeast strain, e.g. *Candida krusei*. Fermentation is carried out under controlled conditions designed to enhance glycerin production. Post fermentation processing includes removal of fat, yeast putty and other impurities in the fermented fluid by centrifugation. The liquid phase is collected for additional purification. Physical methods, such as settling overnight and separation by layers, are used to obtain crude glycerin in the upper layer. At this stage, the glycerin still contains a significant amount of water and/or impurities from the fermentation, which need to be removed in later steps. Larger impurities in the crude glycerin, rapid filtration are removed with a high–efficiency pressure filter. After filtration, glycerin water is concentrated by using a vacuum concentrator to remove excess water. The concentration process involves heating the hot liquid glycerin under pressure and subsequently spraying the glycerin into a vacuum chamber where water evaporates off as steam and glycerin remains a liquid. Following removal from the vacuum concentrator, the glycerin is refined by distillation followed by treatment with fine activated charcoal. Charcoal treatment is repeated to ensure the removal of impurities in the glycerin. Glycerin at this stage is microfiltered and should be perfectly transparent. The filtrate is then subjected to ultrafiltration to remove smaller impurities that may be present. Technical grade glycerin: after filtration, technical grade glycerin is obtained. To obtain USP grade glycerin, the technical grade glycerin is first polished by ion exchange treatment to remove inorganic elements required for growth of the microorganism. Efficient treatment with food-grade ion exchange resins removes both cations (sodium, potassium, calcium, etc.) and anions (chloride, sulfate, phosphate, etc.) without changing the glycerin. Following the ion exchange step, excess moisture in the glycerin is removed by vacuum evaporation. Additional filtration is performed to eliminate all remaining impurities that may be present. At the end of this step, the quality of glycerin meets USP standard, with excellent color stability upon heating.

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.

The earliest written account of soap-making and use was described in Sumerian clay tablets dating back to the 3rd millennium BCE in the Hittite capital of Boghszkoi: “With water I bathed myself, with soda I cleansed myself, with oil from the basin I beautified myself.” Soap-makers including Babylonians, Mesopotamians and Egyptians mixed fats, oils and salts or ash together to make soap: a process that was later termed saponification. Fatty acids combine with soda as soap that separate by the addition of salt and come to the surface in the molten condition. Glycerin is set free and remains dissolved in the spent lye. Until recently, the recovery of glycerin from crude soap lye was the predominant source for glycerin production. Progressive improvements in glycerin production have evolved to include other methods of production ranging from organically produced glycerin to synthetic glycerin produced from petroleum and biodiesel derived precursors.

Natural fats and oils for the production of synthetic glycerin may be products of conventional agriculture (Table 3). However, CFR 205.270 (a), Organic handling requirements, is inclusive for slaughter of animals for fat, the extraction of oils from plants, heating, alkaline mediated catalysis (with salts included in 7 CFR 205.605) and subsequent manufacturing, even though a chemical reaction, i.e., hydrolysis or saponification takes place to produce glycerin. Thus, it has been possible to produce certified organic glycerin from fats and oils derived from certified organic plants and animals.

Louis Pasteur recognized in 1857 that glycerin formed naturally during the alcoholic fermentation of sugars. Glycerin produced by microbiological fermentation requires enzymatic digestion (with enzymes included in 7 CFR 205.605), mixing, formulation (with yeast as described in 7 CFR 205.605), extraction, filtration, and ion exchange. These steps are inclusive in 7 CFR 205.270 (a) Organic handling requirements. Thus, it has been possible to produce certified organic glycerin from certified organic starches, yeasts, and enzymes.

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)).

Glycerin is classified as a synthetic in the National List with the limitation that it be produced from fats and oils. Historically, glycerin was sourced as a byproduct of the soap and candle making industries. However, in recent times glycerin is produced synthetically from petroleum-derived propylene and as a byproduct of biodiesel production. Fats and oils for glycerin production may be the products of conventional agriculture (Table 3). Glycerin can also be produced by fermentation of sugars and starches. However, there is no provision in the standard for glycerin produced by fermentation to be sourced conventionally. Thus, glycerin produced by fermentation must be produced organically for use in organic products.

Because hydrolysis, saponification and fermentation used for the production of glycerin from natural fats, oils and starches meet the requirements for organic handling provided by 7 CFR 205.270, it has been possible to produce certified organic glycerin from which the fats, oils or starches are derived from organically produced animals and plants. Table 5 lists twenty-one handling operations that manufacture and/or source USDA certified organic glycerin. In all cases, glycerin provided by these manufacturers meets or exceeds the requirements for USP glycerin provided in Table 1 for use in foods, cosmetics, and pharmaceuticals and displays the USDA Organic seal.

<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.

According to Title 21 CFR 182.1320 of the federal register, glycerin is a multiple purpose generally recognized as safe (GRAS) food substance when used according to good manufacturing practice.

According to Title 40 CFR 180.1250 of the federal register, glycerin is exempt from a tolerance in foods by the US Environmental Protection Agency. In addition, glycerin is considered a minimal risk ingredient for food in EPA's Title 40 CFR 180.950 (e) specific chemical substances. Residues resulting from the use of the glycerin as either an inert or an active ingredient in a pesticide chemical formulation, including antimicrobial pesticide chemicals, are exempted from the requirement of a tolerance under the Federal Food Drug and Cosmetic Act (FFDCA) section 408, if such use is in accordance with good agricultural or manufacturing practices. Although glycerin produced as a biodiesel by-product has occasionally been implicated in EPA violations involving dumping excessive amounts of glycerin into the environment, details of any an incident involving the production organic glycerin were not found.

<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)).

One of glycerin's many uses is as a preservative. Widely used in formulations for many industries, glycerin (glycerin) is a colorless, odorless, and viscous liquid whose three hydrophilic hydroxyl groups impart both solubility in water and hygroscopicity (water-absorption). Glycerin has excellent anti-bacterial, anti-fungal, and anti-viral properties. It acts as a cryo-protectant, because it binds strongly to water and forestalls the formation of damaging ice crystals. The action of glycerin as a humectant allows the vital character of many herbal extracts to be preserved in solution. Glycerin is often used in the production of herbal extracts where it acts both as solvent and as 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)).

Glycerin's unusual properties make it useful in a great variety of products and processes. Some of these uses depend on its physical properties such as hygroscopicity, viscosity and high boiling point while others depend on its chemical properties. In many cases, it may be a combination of several of its properties, both physical and chemical, which make it applicable, particularly its non-toxicity. As a food it is easily digested; its metabolism places it with the carbohydrates, though it is present in combined form in all vegetable and animal fats.

Glycerin is important as an additive in beverages. It is used in the preparation of soft drinks, tea and coffee extracts, and is a natural ingredient in wine and beers. Louis Pasteur, when performing studies on fermentation in 1885, found that 3.5% of the sugars in alcoholic fermentation are converted to glycerin.

Glycerin is an important flavor constituent in the production of wines. The alcohol-glycerin ratio is often employed as a means of determining adulteration in wine, the ratio being much more important than either constituent. In some wine producing countries, the limits of alcohol-glycerin have been fixed by law. Glycerin, as a by-product of alcoholic fermentation is present in beer to the extent of 0.09 to 0.18 percent and in wine to the extent of about 10%. The addition of glycerin to distilled liquors improved their smoothness and body, and it has been suggested that a small amount of glycerin added to a cocktail would improve the flavor by making a smoother blend of the ingredients. With preparations of saponin and other foam-forming materials, glycerin has been used in heading liquids to produce foam on both carbonated and non-carbonated beverages. Glycerin is used quite extensively in soft drinks and sports drinks. It adds smoothness to the drink and serves as a carrier for flavor extracts. In the same way, it may be used for preparing fountain syrups, vanilla and citrus flavors, coffee, fruit and spice extracts and chocolate syrups. Flavor pastes and powders often contain glycerin, and it is solvent for many food colors. Not only is glycerin an excellent solvent for flavor and taste materials present in natural products, e.g., coffee beans, but it can serve to blend flavors. The addition of glycerin and dextrose to a tea concentrate, the pH of which has been adjusted to 7.7 to 8.0, results in a product that retains its clear, attractive appearance, natural flavor and aroma during extended periods of storage. The function of the glycerin dextrose combination is to solubilize the precipitate that normally forms in cooled liquid tea concentrate. Many agents, sucrose among them, have the same effect, but in the concentration needed for clarity, impart too sweet a taste to the finished drink. A concentrate with an optimum clarity and minimal sweetness is achieved by using 5% glycerin and 15% dextrose. Another use of glycerin in the beverage field is in the manufacture of cork liners for bottle caps. Here the cork is treated with glycerin to maintain softness and pliability, thus preventing shrinkage of the cork, and insuring a tight seal. Whole corks are sometimes treated with glycerin by dipping the cork in the glycerin before inserting it in the wine bottle.

The solvent power of glycerin results in its use in many flavors and extracts, and such use frequently allows the elimination of part or all of the alcohol commonly used in such preparations. It has been used in vanilla flavors, and has been used in chocolate syrups to improve their body and smoothness. Glycerin is also a solvent for many food colors and the USP grade of glycerin, being completely non-toxic, is generally accepted by the Food and Drug Administration as a component of foods, except where specific food standards fail to list it as an optional ingredient. The use of approximately 5% of glycerin in frozen eggs and frozen yolks prevents the formation of gummy lumps in the eggs, and cakes baked with glycerinated eggs have larger volume and better texture than cakes made with non-glycerinated eggs. Glycerin enters into flavoring materials and curing salts and as a plasticizer in the many casings and coatings developed for the meat coating industry. It is used in both animal and artificial casings, the latter being composed essentially of regenerated cellulose. The glycerin increases the flexibility of the casings and their ease of handling and keeps them from drying out during shelf storage.

Jelly-like candies often use glycerin to prevent drying and graining, but it is also used in many other types of candies, particularly fudge, to maintain a soft texture and fine grain. Here the amount used is generally 9 to 10 percent of the weight of the sugar. In other candies, the amount of glycerin may be from 5 to 15 percent of the weight of the sugar, depending on whether the candy should be firm or soft. In the same way, it is used in cake icings. Here it acts to prevent the icing from graining but also from becoming hard and brittle, particularly in such things as wedding cakes where they are prepared ahead and must stand for some time before being cut. Glycerin applied to dried fruits by dipping and spraying will reduce stickiness and inhibit surface crystallization of sugar. For the same reason, a small amount used in jams gives protection against crystallization. A recent development in this line is the preparation of citrus fruit peel for use in baking and other food preparation. In this process, the citrus peel is dehydrated by use of a high solid transfer medium made from dextrose, glycerin, corn syrup and starch. Here the transfer medium becomes the replacement agent, and results in a peel which is semi-translucent, has a natural peel color and retains the essential oils and "bite qualities" of the fresh form. Glycerin, glycerin salt and glycerin invert sugar solutions have been found very satisfactory for direct contact quick freezing. The advantages of aqueous glycerin solutions for this type of freezing are: their suitable viscosities, good heat transfer ability, noncorrosive properties, in proper concentration, resistance to fermentation, their ability to retain natural color, and the fact that they have no objectionable odors or taste. They do not cause excessive rupture of the cells at cut surfaces and result in a natural looking product. Glycerin used for freezing fish has been tested and it has been found that freezing fish before rigor mortise sets in, glycerin at extremely low temperatures reduces the amount of ice formation and hence the tissue protein denaturation. The addition of a small amount of glycerin to peanut butter reduces oil separation and increases the stiffness of the butter. If added to the peanut butter after it is ground it has more effect and does not alter the taste. About 4% by weight of glycerin added to shredded coconut acts as a softener and humectant and keeps the coconut from drying out in the opened package. It is also used in cakes, low fat foods and energy bars to preserve their moisture and retard staling. It gives an increased ratio of volume to weight when used in the proper amount. This will vary with the type of cake, but usually is in the neighborhood of ten percent of the weight of the sugar used. An important but indirect use of glycerin in food processing is in the use of so called "mono-glycerides", which are emulsifiers and stabilizers for many products. They are the products of the reaction of glycerin with a wide variety of fats and fatty acids. The results are actually a mixture of mono-, di- and triglycerides, but they contain a high proportion of the monoglycerides and hence are called by that name. These monoglycerides impart surface activity, making the mixed ester both oil soluble and water dispersible. They are excellent emulsion stabilizers and hence are added to margarine to improve its stability and reduce spattering on heating; to shortenings to increase their plasticity; to dough mixture, to promote dispersion of the fat, help maintain moisture balance in the product and permit richer formulations with longer shelf life. In addition they are used in salad dressings, frozen desserts, candy and food coatings. One important use of these glycerides is as softening and anti-staling agents in the manufacture of white bread that is sliced and wrapped.

The nontoxicity of glycerin as an ingredient of goods and beverages has been established through generations of safe use and clinical and scientific studies. It is recognized as safe by the U.S. Food and Drug Administration when it is of the synthetic product. Of course labeling laws as to ingredients must be followed. The poly-glycerin esters are a more recent commercial development and range from di-glycerin to deca-glycerin esters. These are prepared from poly-glycerins combined with fats and fatty acids. The esters offer a wide range of hydrophilic and lipophilic emulsifiers and are utilized by the body and broken down into glycerin and fatty acids. Besides use in foods, they have applications as emulsifiers in pharmaceutical, cosmetic, and other industrial applications.

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

Glycerin is a valuable aid in formulating a wide range of food products. It is generally hygroscopic, water-soluble and exhibits moderate viscosity at high concentrations in water. When present naturally or when added during processing, it can impart one or more of several beneficial characteristics. These effects include crystallization retardation, improvement of stability on aging, control of viscosity or bodying, preservation, solvency, moisture retention and others. Glycerin occurs in nature. It has been reported to occur in fermented products. Glycerin can add qualities that are desirable for the consumer, such as a texture or a product quality that was not present in the original formula of the product. Some examples are viscosity or bodying agent, crystallization modification, taste or sweetness, hygroscopicity or humectancy, solvency, rehydration aids, sequestering, antioxidant, microbiological preservation softening, bulking agent and dietary foods. Special dietary foods have been designed to help reduce the consumption level of protein, fat, carbohydrate and calories. When conventional foods are modified for dietary purposes, such properties as taste texture and body are sometimes affected. Glycerin is one substance that is considered as a suitable material to be added to dietary foods to improve consumer appeal.

While the viscosity effect is minimal for glycerin when compared with other viscous liquids, it is known that relatively small proportions of glycerin added to beverages convey an improvement in mouth-feel that is described as bodying action. Because many foodstuffs are dependent on semi-equilibrium of sugar crystals and sugar syrup for their texture characteristics, e.g., creams, fondants and fudges and as a result they exhibit a limited shelf life in reference to texture, glycerin is added to lengthen shelf life by further complexing the crystalline nature of the confection and reduce its tendency to harden. This is also true in the production of marshmallows, cake icing, and nougat where the crystalline inhibitory action of glycerin provides advantages in processing. The humectancy of glycerin also helps to keep the marshmallows soft by reducing the rate of moisture loss to the casting starch during production. Glycerin is added to coconut to preserve moisture and softness. Dehydration of foods is important in preservation and reduction in weight for shipment. In many instances food dehydration causes difficulty in rehydration and the rehydrated food is significantly different from the original foodstuff. Glycerin is added to military food to improve rehydration characteristics, but also increases shelf life by retarding free fatty acid acid formation, thus reducing hydrolytic rancidity. Glycerin can be found in soups and broths; soybean-based products; fat-based desserts; dried vegetables like mushrooms and seaweed; bakery products; sausage casings; yeast and yeast products; sauces; and dietetic foods. Glycerin is often mixed with other nutrients such as lecithin or tocopherols and used as a fat emulsifier in foods. Glycerin is used as a preservative, sweetener, thickener, or humectant in many manufactured or processed food products, and is generally regarded as safe to consume. Glycerin is used as a sweetener in food products because it adds a sugary flavor, but contains no sugar. Glycerin is a food additive in fruit and vegetable juices and flavored dairy drinks like chocolate milk, yogurt drinks, cocoa, and eggnog. Glycerin is used to make flavored water beverages, like sports drinks. Dairy products like condensed milk, clotted cream, milk powder, cheeses, puddings, yogurts and dairy spreads contain glycerin. Glycerin is used as a lubricant in chewing gum and pellet food processing. Soft candies contain glycerin to keep them moist. Candies that are labeled sugar-free may actually contain glycerin, because it adds the sweetness needed for the candy. Glycerin is found in a variety of condiments, like mustard and vinegar. Glycerin is also found in mixed spices and seasonings. Many processed foods contain glycerin, including rice cakes; processed meats, poultry and game products; processed cheese; and dried fruit contain glycerin. Other processed foods like cereals, pastas, batters and starch based desserts also contain glycerin.

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)).

Glycerin occurs naturally in varied combined forms as a simple, mixed or complex glyceride in association with fatty acids, carbohydrates, phosphate or amino acid. It rarely exists in significant amounts in the free form in natural fats or oils of animal, vegetable, marine or biological origin. Glycerin constitutes about 10% of the lipid molecule. Natural glycerin is isolated as a by-product from the hydrolysis of fats and oils during the manufacture of soaps, etc. Trace contaminants include fatty acids, their esters, and processing chemicals including background levels of heavy metals. It is important to use very pure alkalis for saponification in order to avoid the introduction of sulfites, sulfides and arsenic that are very hard to remove once added to glycerin. Glycerin, USP shall be free from contamination with heavy metals. Table 1 indicates a tolerance of less than 5 ppm for heavy metals.

The FDA (http://www.fda.gov/downloads/ForIndustry/IndustryNoticesandGuidanceDocuments/UCM310867.pdf) has issued notifications to industry concerning specific contamination issues that present for glycerin use. One concerns toxic compounds that may contaminate glycerin produced from Jatropha oil or by fermentation of Jatropha. Jatropha is a drought-resistant shrub that grows well in tropical and semi-tropical climates throughout the world. The Jatropha plant may be commonly used in biodiesel fuel production through the extraction of its oil. When vegetable oils and animal fats are used in biodiesel fuel production, the co-products include oils, glycerin, and protein. However, unlike other benign materials used to produce biodiesel fuel, Jatropha plants may contain toxic compounds. Consequently, the oils, glycerin, and protein sourced from Jatropha seeds may also contain toxic compounds. Although crude Jatropha extracts have protein levels comparable to soybeans and could be an attractive protein source for humans and animals, Jatropha-derived protein may contain toxic ingredients. The presence of these toxins might go undetected using conventional impurity test methods.

The potential presence of diethylene glycol in glycerin has prompted the FDA to issue guidance to industry (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070347.pdf) for potential contamination. The guidance provides a requirement for an identity test to be performed on glycerin that includes a limit test for diethylene glycol (DEG —Table 1). The guidance was made in response to a several poisonings involving glycerin. A 1937 outbreak of DEG poisoning occurred in the United States, which resulted from people ingesting elixir of sulfanilamide that contained DEG as a solvent. One hundred and seven people died, many of them children. This event led to the enactment of the Federal Food, Drug, and Cosmetic Act (the Act), which included a provision requiring that drugs be demonstrated to be safe before marketing. In late 1995 and early 1996, many children were admitted to hospitals in Port-au-Prince, Haiti, with sudden kidney failure, resulting in at least 80 fatalities. An investigation by Haitian health officials, the Centers for Disease Control (CDC), and FDA discovered that the cause was DEG-contaminated glycerin in acetaminophen syrup manufactured in Haiti. Between 1990 and 1998, similar incidents of DEG poisoning occurred in Argentina, Bangladesh, India, and Nigeria and resulted in the deaths of hundreds of children. In October 2006, an outbreak of DEG poisoning occurred in Panama, resulting in multiple cases of illness and death.

These cases reveal the following similarities:

- The pharmaceutical manufacturers of the syrups that contained contaminated glycerin did not perform full identity testing on the glycerin raw material, including tests to quantify the amount of DEG present and to verify the purity of the glycerin received.
- The pharmaceutical manufacturers of the syrups containing contaminated glycerin relied on the certificate of analysis (COA) provided by the supplier.
- The origin of the glycerin was not easily apparent from the COA. The COA obtained by the pharmaceutical manufacturers of the syrups was often a copy of a COA on the letterhead of the distributor and not the COA provided by the manufacturer of the glycerin. The chain of custody or distribution history of the glycerin was also not readily known because the glycerin may have been sold several times between its manufacture and its use in medicinal syrup or other drug product.

Because of these practices, DEG-contaminated glycerin entered the pharmaceutical raw material supply chain.

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

Glycerin (CAS no. 56-81-5) is a liquid at room temperature and has physical–chemical properties and characteristics given in Table 4. For vapor pressure, a measured value at 50°C is available. At this temperature, vapor pressure is very low.

Glycerin may be released into the environment during production processing and use. Small amounts of glycerin may be released from through production and processing, that will typically be treated by the production site's wastewater treatment plant. Glycerin can enter the aqueous and terrestrial environment from end uses such as in cosmetics and pharmaceutical products and down hole lubricants for oil and gas fields. There is little likelihood of emissions to the atmosphere from production, processing or downstream use. The calculated photo-oxidation half-life in air is 6.8 hours. Glycerin is readily biodegradable, and will partition into the water phase. It is readily degraded by microorganism under both aerobic and anaerobic conditions. Glycerin is not expected to bioaccumulate.

There are no structural alerts that raise concern for the inherent mutagenic potential of glycerin. In vitro, glycerin was negative (with and without metabolic activation) in Ames tests and did not induce chromosomal effects in mammalian cells. The responses seen in a limited gene mutation study in mammalian cells are of uncertain biological relevance, as the doses were not maximized. Only two in vivo studies are available. A negative result was observed in a chromosome aberration test, and an increase (not statistically significant) in post implantation loss was seen in a rat dominant lethal assay. However, for both assays, the limited details reported and absence of a positive control, mean no reliable conclusions can be drawn from the in vivo data. Thus, there is no in vitro or in vivo data indicating glycerin has a genotoxic potential.

Glycerin is of low acute toxicity to fish and aquatic invertebrates. Lethal concentration (LC)/maximum effective concentration $(EC)_{50}$ values are all in excess of 5000 mg/L. Glycerin is also of low acute/chronic toxicity to algae and bacteria with an EC_0 of 3200-10,000 mg/L. Based on information available glycerin is of low hazard to the aquatic environment. There is significant data available indicating that glycerin is of low concern as an environmental hazard.

According to Title 40 CFR 180.950 of the federal register, glycerin is exempt from a tolerance by the US Environmental Protection Agency. This means that glycerin can be present in any amount in pesticide or crop treatment preparations. Production of palm and coconut oil, starting material for glycerin manufacture from oils has been associated with deforestation of tropical rain forests. [1]

Table 4 Summary of physico-chemical properties

PROPERTY	VALUE
Physical form	Liquid
Purity	95 – 99.5% (water as an impurity with trace levels of polyglycerin)
Melting point	18°C
Boiling point	290°C at 1013 hPa
Relative density	1.26 at 20°C
Vapor pressure	0.000106 hPa at 25 Deg C (calculated) and 0.0033 hPa at 50°C (measured)
n-octanol –water partition coefficient	log K_{OW} - 1.76 K_{ow}=octanol-water partition coefficient
Water solubility	Miscible
Dissociation constant	0.07E-13
Flash point	160°C
Autoflammability	393°C
Viscosity	1410 mPa s at 20°C
Surface tension	63.4 mN/m at 20°C mN=milliNewtons

<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)).

Glycerin is widely used and can be found in many industrial, professional and consumer products. There is a potential for occupational exposure through inhalation and skin contact. Consumers may be exposed to glycerin by the oral and dermal routes of exposure. Smoking may lead to an additional glycerin uptake by inhalation. Glycerin is absorbed following ingestion and incorporated in the standard metabolic pathways to form glucose and glycogen. The weight of evidence indicates that glycerin is of low toxicity when ingested, inhaled or in contact with the skin. Glycerin is of a low order of acute oral and dermal toxicity with LD_{50} values in excess of 4000 mg/kg body weight. At very high dose levels, the signs of toxicity include tremor and hyperaemia of the gastro-intestinal tract. Skin and eye irritation studies indicate that glycerin has low potential to irritate the skin and the eye. The available human and animal data, together with the very widespread potential for exposure and the absence of case reports of sensitization, indicate that glycerin is not a skin sensitizer.

Repeated oral exposure to glycerin does not induce adverse effects other than local irritation of the gastro-intestinal tract. A 2-year study, established the overall "no observable effects limit (NOEL)" after prolonged treatment with glycerin of 10,000 mg/kg body weight (20% in diet), which is in agreement with the findings in other studies. At this dose level, no systemic or local effects were observed. For inhalation

[1] Gilbert et al., 2012; Carlsona et al., 2012.

exposure to aerosols, there is evidence of local irritant effects at and above 662 mg/m^3. The no observable adverse effects (NOAEL) limit is 167 mg/m^3.

Glycerin does not induce gene mutations in bacterial strains, chromosomal effects in mammalian cells or primary DNA damage in vitro. Results seen in a limited mammalian gene mutations test were of uncertain biological relevance. In vivo, glycerin produced no statistically significant effect in a chromosome aberrations and dominant lethal study. However, the limited details provided and absence of a positive control prevent any reliable conclusions can be drawn from the in vivo data. Overall, glycerin is not considered to possess genotoxic potential.

The experimental data from a limited dietary study in the rat does not provide any basis for concerns in relation to carcinogenicity. Data from non-guideline studies designed to investigate tumor promotion activity in male mice suggest that oral administration of glycerin up to 20 weeks had a weak promotion effect on the incidence of tumor formation.

No effects on fertility and reproductive performance were observed in a two-generation study with glycerin administered by oral gavage (NOAEL 2000 mg/kg body weight). No maternal toxicity or teratogenic effects were seen in the rat, mouse or rabbit at the highest dose levels tested in a guideline comparable teratogenicity study (NOEL 1180 mg/kg body weight).

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

Glycerin is a polyhydric alcohol. Polyhydric alcohols are in general valuable aids in the formulation of a wide variety of food products. Examples of use are as a humectant, a solvent, an emollient, a sweetener, a bodying agent, a preservative, filler in low fat foods, an alcohol free solvent for botanical extracts, cosmetics and pharmaceutical agents, a thickening agent in liqueurs, a hydrating agent used in sports and energy drinks and in the manufacture of cellophane, cosmetics and meat casings. They may be present naturally as is the case for wines, beers, and some fermented foods or added to a food product to impart one or more beneficial characteristics. Other polyhydric alcohols include propylene glycol, butylene glycol, sorbitol, erythritol, mannitol, arabitol, ribitol, xylose, volemitol, and perseitol. In addition to the polyhydric alcohols some sugars, starches, pectins and gums may be used as thickeners, bulking agents and/or fillers. There are also a number of alternative sweeteners available. With respect to functionality, certified organic glycerin is also available and can be substituted for every application in which synthetic glycerin is currently used.

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)).

Currently certified USDA organic operations able to potentially source organic raw materials to replace the use of synthetic glycerin in organic foods include 803 beef, 72 pork, 2244 soybean, 4559 corn, 52 canola, 24 cotton seed, 265 peanut, 283 coconut, 24 linseed, 600 olive, 35 flaxseed, 120 palm, 2 castor bean, 575 sunflower, 21 starch, 4 enzyme and 3 seafood operations. There are currently 21 certified USDA organic glycerin operations (Table 5). In addition, naturally sourced polyols such as mannitol, arabitol or sorbitol; naturally source sugars; natural sweeteners; pectins; gums and natural starches may be used in place of synthetic glycerin for many of its uses. One example is brown rice syrup.

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

Glycerin can be produced organically by the process of microbial fermentation using only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). In addition, certified organic glycerin can be produced by hydrolysis of organic fats and oils using either steam splitting or traditional saponification with a catalytic amount of an alkali (sodium carbonate, sodium hydroxide, or potassium hydroxide) on the National List. There are currently 21 USDA certified organic operations supplying glycerin for organic food or cosmetic products.

Table 5 Handling Operations that Manufacture and/or Source USDA Certified Organic Glycerin*

Ref#	Certifying Agent	Operations	Certificate No.	State	Country
3229	Ecocert S.A.	Interaxion	007FR-INTERAXION-1200z1e		France
3267	Ecocert S.A.	Ies Laboratoire	007FR-IES LABO-1100z1e		France
3429	Ecocert S.A.	Cremer Oleo Gmbh & Co.kg	121127 Cremer Pleo NOP z1e	Hamburg	Germany
8338	ICS - International Certification Services, Inc.	Boghosian Raisin Packing Company, Inc	0497050	California	United States of America (USA)
2643	ICS - International Certification Services, Inc.	Draco Natural Products	0504335		China
16967	New Jersey Department of Agriculture	Kinetik Technologies, Inc	H037	New Jersey	United States of America (USA)
17915	OneCert	Parchem	596	New York	United States of America (USA)
19643	Oregon Tilth	Mountain Rose Herbs	Ot-006943	Oregon	United States of America (USA)
19920	Oregon Tilth	Essential Wholesale - Essential Labs - Fioravanti Custom Products, LLC	Ot-003056	Oregon	United States of America (USA)
17914	Oregon Tilth	Kic Chemicals, Inc.	Ot-005298	New York	United States of America (USA)
16985	Oregon Tilth	International Foodcraft Corporation dba Ifc Solutions	Ot-004783	New Jersey	United States of America (USA)
17022	Oregon Tilth	Elan, Inc.	Ot-002911	New Jersey	United States of America (USA)
17023	Oregon Tilth	Organic Flavors & Fragrances Inc.	Ot-007539	New Jersey	United States of America (USA)
9096	Oregon Tilth	Oh, Oh Organic, Inc.	Ot-011305	California	United States of America (USA)
10333	Oregon Tilth	Marroquin Organic International, Inc.	Ot-006265	California	United States of America (USA)
12886	Oregon Tilth	The Lebermuth Company., Inc.	Ot-011492	Indiana	United States of America (USA)
13366	Oregon Tilth	Amrita Aromatherapy, Inc.	Ot-000300	Iowa	United States of America (USA)
14074	Oregon Tilth	Owen Botanical Organics, Inc.	Ot-007643	Louisiana	United States of America (USA)
14783	Oregon Tilth	Navada Imports, LLC	Ot-012040	Massachusetts	United States of America (USA)
15746	Oregon Tilth	Intelligent Nutrients	Ot-004775	Minnesota	United States of America (USA)
17171	Organic Certifiers, Inc.	Mel-co	12471	New Mexico	United States of America (USA)

*This table contains information about operations that were certified to the National Organic Program regulations as of January 2, 2013. For more up-to-date information about certified organic operations, please contact their certifying agent directly.

References

Carlsona, K. M., Currana, L. M., Ratnasarie, D., Pittmana, A. M., Soares-Filhof, B. S., Asnerg, G. P. , Triggh, S. N. , Gaveaub, D. A., Lawrencei, D. and Rodrigues, H. O. (2012) Committed carbon emissions, deforestation, and community land conversion from oil palm plantation expansion in West Kalimantan, Indonesia, proceedings of the National Academy of Science, 109:19, pp. 7559-7564.

Cong Chen, Wei Zhong Li, Yong Chen Song, Jian Yang (2009) Hydrogen bonding analysis of glycerin aqueous solutions: A molecular simulation study, Journal of Molecular Lipids, 146:23-28.

Codex Alimnentarius (1999) Guidelines for the production, processing, labeling, and marketing of organically produced foods, GL 32-1999, p. 26.

Food and Agriculture Organization (1976) Toxicological Evaluation of Certain Food Additives: Glycerin and glycerin diacetate, Twentieth Report of the Joint FAO/WHO Expert Committee on Food Additives, Geneva, 1976, WHO Technical Report Series No. 599, FAO Food and Nutrition Series No. 1, pp. 1-2

Gilbert, Natasha (2012) Palm-oil boom raises conservation concerns, Nature, 487:7405, pp. 14-15

Glycerin (CID 753)—Bolton E, Wang Y, Thiessen PA, Bryant SH. PubChem: Integrated Platform of Small Molecules and Biological Activities. Chapter 12 IN Annual Reports in Computational Chemistry, Volume 4, American Chemical Society, Washington, DC, 2008 Apr. [free author manuscript]

Government of Canada, Canadian General Standards Board (2011) Organic Production Systems permitted Substances Lists (ICS 67.040), CAN/CGSB-32-311-2006, p17.

Griffin, William C. and Lynch, Matthew L., (1972) Chapter 10, Polyhydric Alcohols *in* Handbook of Food Additives, Furia, T.E. ed., CRC Press, West Palm Beach, FL, pp. 431-455

Hong-Juan Liu, De-Hua Liu and Jian-Jiang Zhong (2003) Novel Fermentation Strategy for Enhancing Glycerin Production by *Candida krusei*, Biotechnol. Prog.(19):1615-1619.

Jakobsen, G, Kathagan, FW, Klatt, M (1989) Glycerin *in* "Ullman's Encyclopedia of Industrial Chemistry," Weinheim, Munich, 447-489.

Lenth, C.W. and DuPuis, R.N. (1945) Polyhydric Alcohol Production, Industrial and Engineering Chemistry, 37 (2) pp. 152-157.

Martin, G and Strausz, HJ (1956) The manufacture of glycerin, vol. iii the modern soap and detergent industry, The Technical Press, LTD., London.

Morrison, LR (1994) Glycerin *in* Encyclopedia of Chemical Technology, Wiley, New York, 681-694.

Pasteur, Louis (1858) Production constant de glycerin dans la fermentation alcoolique, Modes et cultures: comptes rendus des séance Academie des sciences d'outre-mer, 46:857.

Riddle, Jim (2005) NOSB guidance for the review of synthetic and non-synthetic substances

Robertson, Steve (2002) Glycerin: Organization for Economic Cooperation and Development Screening Information Data Set, OECD Screening Information Assessment Meeting 14, Paris, France.

Routh, Hirak Behari, Bhowmik, Kazal Rekha, Parish, Lawrence Charles and Witkowski, JosephA. (1996) Soaps: From the Phoenicians to the 20th Century—A Historical Review, Clinics in Dermatology, 14:3-6.

The Glycerine Producer's Association (1963) Uses of Glycerine, pp.-29.

Thwaites, JD (1969) Glycerin—production and uses, Chem and Industry, 30:1002-1006.

US Department of Health and Human Services, Food and Drug Administration (2012) Notification to Industry: products using oils, glycerin or water that were derived from the Jatropha plant may have toxic effects, p. 1-2.

US Department of Health and Human Services, Food and Drug Administration (2007) Guidance for Industry Testing of Glycerin for Diethylene Glycol, p. 1-4.

US Pharmacopeial Convention (2013) Glycerin Monograph Revision-2009, Rockville, MD (Appendix 2).

Wang, Zheng-Xiang, Zhuge, Jian, Fang, Huiying and Prior, Bernard A. (2001) Glycerin production by microbial fermentation: A review, Biotechnology Advances, 19 (2001) 201–223.

Wang, ZX, Zhuge, J, Fang, H., Prior, BA (2001) Glycerin production by microbial fermentation: a review, Biotechnol. Adv. Jun 19(3):201-23.

Wu, Jerry, Quirk, Brien and Wang, Tian X. (2010) Patent application title: Method of producing organic certified glycerin, pat. Appl. No.-20100144892