



**Providing World-Class, Natural Products
To Improve People's Lives**

January 15, 2007

Mark Bradley
USDA AMS T&M
Room 4009-SB STOP 0292
1400 Independence Avenue SW
Washington, DC 20250-0292

Dear Mr. Bradley,

I have enclosed San Joaquin Valley Concentrates' petition for the inclusion of Grape Seed Extract on the National List of materials approved for use in and on organic products under Section 205.606 of the National Organic Program.

I appreciate your efforts to have the National Organic Standards Board review Grape Seed Extract prior to the June deadline requiring a positive listing for non-organic, agricultural products that are not commercially unavailable in organic form. A timely decision to include Grape Seed Extract under Section 205.606 will assure that this very important ingredient remains available to US organic processors and to organic consumers, worldwide.

Please do not hesitate to contact me with any questions, or if I can clarify any information contained in the petition.

Respectfully submitted,

Phil Castro
San Joaquin Valley Concentrates
Extract Manager
559-458-2588



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**San Joaquin Valley Concentrates
Petition for the Inclusion of Grape Seed Extract to the National List under
Section 205.606 of the National Organic Program
January 15, 2007**

ITEM A - Petition for the inclusion of Grape Seed Extract on the National List.

X Section 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic" or "made with organic ingredients)

ITEM B

1. The substance's common name: **ActiVin Grape Seed Extract**

2. The manufacturer's name, address and telephone number

San Joaquin Valley Concentrates
5631 E Olive Ave
Fresno, CA 93722
559-458-2588

3. The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer or disinfectant:

Grape Seed Extract is a high grade, high solubility, readily dispersible proanthocyanidin. It is a 100% pure grape seed extract for use in foods, beverages, and dietary supplements applications. (Natural Antioxidant)

4. A list of the crop, livestock or handling activities for which the substance will be used. If used for crops or livestock, the substance's rate and method of application must be described

Grape Seed Extract is a natural antioxidant that delivers Oligomeric Proanthocyanidins (OPC) to organic "Heart Healthy" food products

5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product:

See Attached CBI Flow Diagram and Narrative

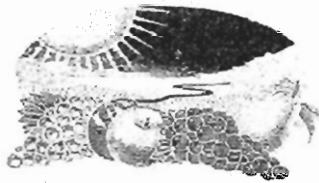
6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance:

See attached FDA GRAS GRN 000124

7. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers:

See attached FDA GRN 000124

SAN JOAQUIN VALLEY CONCENTRATES, 5631 E. OLIVE AVE., FRESNO, CA 93727
TOLL FREE:(800)557-0220 OFFICE:(559)458-2500 FAX:(559)458-2564



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8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance

N/A. Grape Seed Extract is a natural product.

9. The substance's physical properties and chemical mode of action including (a) chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use or manufacture; (d) effects on human health; and, (e) effects on soil organisms, crops, or livestock :

See attached FDA GRN 000124

10. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies:

See attached MSDS

11. Research information about the substance, which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List.

See Attached MSDS FDA GRN 000124

12. "Petition Justification Statement"

GRAPE SEED EXTRACT

Grape Seed Extract is an essential Oxygen Radical Absorption Capacity (ORAC)) ingredient in "heart healthy" products. Grape Seed Extract is a natural source of Oligomeric Proanthocyanidins (OPC). Grape Seed Extract contains the highest ORAC values. It is they most concentrated source of antioxidants and is, by far, the highest source of Oligomeric Proanthocyanidins (OPC) in other sources that include wine , rapeseed oil, grapes, blueberries and cranberries. Grape Seed Extract is important to the organic processing industry because it does not impart an off flavor to the finished product.

Handling practices used in the production of Grape Seed Extract are compatible with Section 205.207

There are no known global sources of organic grape seed extract. Because of the large volumes of seeds required, extremely capital intensive processes and very low yields (100 units of raw material to 1 unit of finished product) of Grape Seed Extract, it is not commercially available in accordance with Section 205.606.

Grape Seed extract is an important environmental use of grape seeds that historically have been considered processing waste. The production of grape seed extract adds economic value to a previously discarded post-processing product.

13. San Joaquin Valley Concentrates has attached a Confidential Business Information Flow Chart and Proprietary Processing narrative. These documents are marked "CBI COPY"



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EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

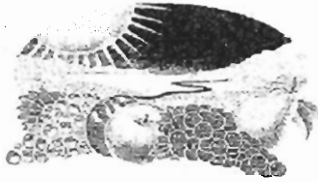
Category 1. Adverse impacts on humans or the environment?

Substance : ActiVin Grape Seed Extract

Documentation

1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]
NO
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]
NO – It is beneficial as it further processes a previously discarded processing waste..
3. Is the substance harmful to the environment? (1)(A)(i);6517(c)(2)(A)i
NO It is beneficial as it further processes a previously discarded processing waste material]
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]
NO
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]
NO
6. Are there adverse biological and chemical interactions in agroecosystem? [§6518 m.5]
NO
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]
NO
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]
NO
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]
NO
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i;
§6518 m.4]
NO
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]
NO See attached FDA GRAS - 000124
12. Is the substance GRAS when used according to FDA's good manufacturing practices?
[§205.600 b.5]
YES
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances?
[§205.600 b.5]
NO

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EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 2. Is the Substance Essential for Organic Production?

Substance **ActiVin Grape Seed Extract**

Documentation

1. Is there a natural source of the substance? [§205.600 b.1]

Grape Seed Extract is a natural source

2. Is there an organic substitute? [§205.600 b.1]

NO Grape Seed Extract is a natural source, and is not commercially available from organic sources

3. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]

Grape Seed Extract is an essential in Oxygen Radical Absorption Capacity (ORAC) ingredient in "heart healthy products.

4. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]

Grape Seed Extract is a Natural Product

5. Is the substance used in handling, not synthetic, but not organically produced?

[§6517 c (1)(B)(iii)]

YES

6. Is there any alternative substances? [§6518 m.6]

Grape Seed Extract is the highest in ORAC values and is important to the organic processing industry because it does not impart an off flavor to the finished product. It is they most concentrated source of antioxidants and is, by far, the highest source of Oligomeric Proanthocyanidins (OPC) in other sources that include wine , rapeseed oil, grapes, blueberries and cranberries.

7. Is there another practice that would make the substance unnecessary? [§6518 m.6]

NO, there are no other natural product available to compare to the concentrated OPC levels of Grape Seed Extract

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 3. Is the substance compatible with organic production practices?

Substance ActiVin Grape Seed Extract

Documentation

1. Is the substance compatible with organic handling? [§205.600 b.2]

Yes – Handling practices used in the production of Grape Seed Extract are compatible with Section 205.207

2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]

Yes—There are no known global sources of organic grape seed extract. Because of the large volumes of seeds required, the extremely capital intensive nature of the process and very low yields of Grape Seed Extract (100 Parts of Raw to 1 Part of Finished Ingredient), it is not commercially available as organic in accordance with Section 205.606. There are only two sources of FDA approved Grapes Seed Extract and neither producer offers certified organic Grape Seed Extract.

3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]

Yes—Grape Seed extract is an important environmental use of grape seeds that are historically considered processing waste. The production of grape seed extract adds economic value to a previously discarded post-processing product.

4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]

YES

5. Is the primary use as a preservative? [§205.600 b.4]

NO

6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]

Primary use is to increase the “natural antioxidant” Oligomeric Proanthocyanidins (OPC). Grape seed extract is a source of a group of colorless flavonoids.

7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:

NO to ALL BELOW

- a. copper and sulfur compounds;
- b. toxins derived from bacteria;
- c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?
- d. livestock parasiticides and medicines?
- e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?



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Description of Process Flow Chart for ActiVin Grape Seed Extract

Confidential Business Information (CBI) January 2007

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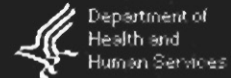
Activin Grape Seed Extract

Process Flow

Confidential
Business
Information
January 2007



U.S. Food and Drug Administration



CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

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CFSAN/Office of Food Additive Safety
August 1, 2003

Agency Response Letter GRAS Notice No. GRN 000124

Mr. Steven J. Anderson
Vice President
San Joaquin Valley Concentrates
5631 East Olive Avenue
Fresno, CA 93727

Re: GRAS Notice No. GRN 000124

Dear Mr. Anderson:

The Food and Drug Administration (FDA) is responding to the notice, dated January 28, 2003, that you submitted in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received the notice on February 3, 2003, filed it on February 14, 2003, and designated it as GRAS Notice No. GRN 000124.

The subject of the notice is grape seed extract (GSE). The notice informs FDA of the view of San Joaquin Valley Concentrates (San Joaquin) that GSE is GRAS, through scientific procedures, for use in beverages and beverage bases, breakfast cereals, fats and oils, frozen dairy desserts and mixes, grain products, milk (whole and skim), milk products, processed fruits and fruit juices at levels ranging from 0.01 to 0.08 percent. In oil/water systems, GSE functions as an antioxidant and as an emulsifier; in aqueous solutions, GSE functions as an antioxidant. San Joaquin notes that the astringent flavor that is associated with use levels greater than 0.05 percent makes the use of GSE self-limiting.

As part of its notice, San Joaquin includes the report of a panel of individuals (San Joaquin's GRAS panel) who evaluated the data and information that are the basis for San Joaquin's GRAS determination. San Joaquin considers the members of its GRAS panel to be qualified by scientific training and experience to evaluate the safety of substances added to food. San Joaquin's GRAS panel evaluated estimates of dietary exposure, method of manufacture, and product specifications as well as published studies on San Joaquin's GSE and other grape seed extract products or components. Based on this review, San Joaquin's GRAS panel concluded that GSE, meeting food grade specifications and produced in compliance with good manufacturing practice, is GRAS,

through scientific procedures, as an antioxidant and/or emulsifier in conventional foods under the conditions of its intended use.

San Joaquin describes GSE as a soluble, rose-brown powder that is a complex mixture of polyphenolic compounds, trace amounts of lipids and protein and small amounts of polysaccharides. Polyphenols are commonly found in higher plants, and are a diverse group of polymeric compounds containing multiple phenolic functionalities. Polyphenols are classified according to their repeating monomeric building blocks. In GSE, these monomers generally fall into two classes, i.e., flavonoids and non-flavonoids. The flavonoid polymers that are known as proanthocyanidins contain a specific type of flavonoid (called flavanols) as monomers. The non-flavonoid polymers are composed of esters of the monomers gallic acid or hexahydroxydiphenyl and a polyol (such as D-glucose). Other non-flavonoid polyphenols can be found in GSE and are composed of the monomers caffeic acid, chlorogenic acid and resveratrol.

San Joaquin notes that GSE is composed of approximately 74 to 78 percent proanthocyanidins and less than approximately 6 percent of free flavanol monomers on a dry weight basis. Specifically, San Joaquin states that GSE contains the flavanol monomers (+)-catechin, (-)-epicatechin, (-)-epicatechin gallate (ECG), (-)-epigallocatechin (EGC), and (-)-epigallocatechin gallate (EGCG).

San Joaquin describes the method of manufacture for GSE. Seeds obtained from grapes (*Vitis vinifera*) are purified, dried, and extracted with deionized water under heat and increased pressure. The aqueous extract is ultrafiltered to remove suspended solids and applied to a chromatographic column that adsorbs the proanthocyanidins. The adsorbed proanthocyanidins are eluted from the column with ethanol and then concentrated by nanofiltration and/or evaporation. The concentrated proanthocyanidin extract is dried to remove residual water and ethanol, ground to particle-sized specifications, blended, and packaged. San Joaquin reports that all materials involved in the manufacturing process are appropriate for food use. San Joaquin provides product specifications for GSE. Specifications include limits on the maximum levels of total phenols (gallic acid equivalents), total monomers, loss on drying, protein, ash, fat, polysaccharides, heavy metals, and microbial contaminants.

Using the United States Department of Agriculture 1994-1996 Continuing Surveys of Food Intakes by Individuals and the 1998 Supplemental Children's Survey, San Joaquin estimates the intake of GSE for the total population from San Joaquin's intended use of GSE would be approximately 150 milligrams per person per day (mg/person/day) at the mean (equivalent to approximately 3 milligrams per kilogram body weight per day (mg/kg body weight/day)) and approximately 300 mg/person/day at the 90th percentile (equivalent to approximately 6 mg/kg body weight/day). San Joaquin also estimates that the current per capita consumption of total proanthocyanidins and total flavanol monomers (from foods including tea, wine, beer, fruits and fruit juices, and chocolate) is approximately 500 mg/person/day and approximately 220 mg/person/day, respectively. San Joaquin concludes that the estimated intake of GSE would be similar to or less than the current dietary intake of total proanthocyanidins and total flavanol monomers from their natural occurrence in food.

San Joaquin discusses published information related to the absorption, distribution, metabolism, and excretion of proanthocyanidins. Although intact proanthocyanidins are poorly absorbed across the intestinal lumen, they may be hydrolyzed in the upper intestinal tract or degraded by intestinal microflora. When proanthocyanidins are absorbed, they and their metabolites are transported to the liver and other organs (e.g., kidney, lung, spleen, and connective tissue) where they are further metabolized and subsequently eliminated via urine, feces, biliary excretion, and respiration.

San Joaquin discusses published studies conducted with San Joaquin's GSE and other grape seed extract products or components in humans and various animal species and draws the following conclusions:

- Acute, subchronic and chronic oral toxicity studies conducted in animals fed GSE, other grape seed extracts, or substances that are components of GSE showed no relevant compound-related toxicological effects.
- Genotoxicity studies conducted in vivo or in vitro with commercial grape seed extracts or substances that are components of GSE demonstrated no mutagenic effects.
- Reproductive and developmental toxicity studies conducted in animals fed (+)-catechin demonstrated no adverse effects.
- Clinical, epidemiological and nutritional studies conducted with substances that are components of GSE demonstrated no significant adverse effects.

San Joaquin reports that GSE was evaluated by the Flavor and Extract Manufacturer's Association and was found to be acceptable for use as a flavoring agent at levels of 100 to 200 parts per million in fruit based beverages, powdered drink mixes, salad dressings, frozen desserts, cultured dairy products and skimmed milk.

Potential labeling issues

Section 403(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA) provides that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. Section 403(i)(2) of the FFDCA provides that a food shall be deemed to be misbranded unless its label bears the common or usual name of each ingredient. In addition, section 403(k) of the FFDCA provides that a food shall be deemed to be misbranded if it bears or contains any chemical preservative, unless it bears labeling stating that fact. San Joaquin's use of GSE as an antioxidant constitutes use as a preservative. Therefore, the ingredient statement on labels of food products treated with GSE must comply with 21 CFR 101.22(j), which requires a food to which a chemical preservative is added to bear a label declaration stating both the common or usual name of the ingredient and a separate description of its function. If you have any questions about the appropriate labeling of this food ingredient, you should contact the staff in the Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS), Division of Food Labeling and Standards, 5100 Paint Branch Parkway, College Park, MD 20740. You can also reach this division by telephone at (301)436-2375.

In addition, Section 403(r) of the FFDCA lays out the statutory framework for a health claim. In describing the intended use of GSE and in describing the information that San Joaquin relies on to conclude that GSE is GRAS under the conditions of its intended use, San Joaquin raises potential labeling issues under these provisions of the FFDCA. These labeling issues consist of San Joaquin's assertion that GSE has physiological effects that San Joaquin views as beneficial. If products that contain GSE bear any claims about such benefits on the label or in labeling, such claims are the purview of ONPLDS. The Office of Food Additive Safety (OFAS) neither consulted with ONPLDS on these labeling issues nor evaluated the information in San Joaquin's notice to determine whether it would support any claims made about GSE on the label or in labeling.

Standards of identity

In its notice, San Joaquin states its intention to use GSE in several food categories, including foods for which standards of identity exist, located in Title 21 of the Code of Federal Regulations. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity. If you have any questions about the use of GSE in standardized foods that would

be marketed in the United States, you should contact the staff in ONPLDS, Division of Food Labeling and Standards

Conclusions

Based on the information provided by San Joaquin, as well as other information available to FDA, the agency has no questions at this time regarding San Joaquin's conclusion that GSE is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of GSE. As always, it is the continuing responsibility of San Joaquin to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter, as well as a copy of the information in your notice that conforms to the information in proposed 21 CFR 170.36(c)(1), is available for public review and copying on the homepage of the Office of Food Additive Safety (on the Internet at <http://www.cfsan.fda.gov/~lrd/foodadd.html>).

Sincerely,

/s/

Laura M. Tarantino, Ph.D.
Acting Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

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FDA/Center for Food Safety & Applied Nutrition
Hypertext updated by [amp/rxm/lah/pmg](#) September 22, 2003

MSDS Material Safety Data Sheet

San Joaquin Valley Concentrates
5631 E. Olive Ave.
Fresno, CA 93727 USA
559-458-2500

ACTIVIN™

100% Grape Seed Extract

1. Product Identification

Appearance: Dark Brown Powder
Classification: Organic, Nutritive
Description: Proanthocyanidin Grape Seed (*Vitis vinifera*) Extract
Trade Name: Activin™
Product Code: GSE-2000, GSE-2000-HD
Order Code: FG13000
Research Code: IH636

2. Composition/Information on Ingredients

Phenols (Gallic Acid Equivalents) of Solids 80 – 95%

3. Hazards Identification

None.

4. Potential Health Effects

INGESTION: Activin Oral LD₅₀ (rat) is >5000 mg solids/kg.

INHALATION: May cause irritation of mucous membranes.

SKIN CONTACT: No known risk.

EYE CONTACT: Direct contact can cause irritation of the conjunctiva, cornea and iris.

5. First Aid Measures

INGESTION: Drink plenty of water. If any discomfort persists, obtain medical attention.

INHALATION: Remove victim to fresh air. If breathing is difficult or if any discomfort persists, obtain medical attention.

SKIN CONTACT: Wash with soap and water.

EYE CONTACT: Flush with clean water. If irritation persists obtain medical attention.

6. Fire Fighting Measures

FIRE AND EXPLOSION HAZARD: None.

HAZARDOUS DECOMPOSITION PRODUCTS: None known.

STABILITY: Stable.

FLASH POINT: Not applicable

FLAMMABLE LIMITS (Air): Not applicable

EXTINGUISHING MEDIA: WATER

FIRE FIGHTING PROCEDURES: For fires involving this material, do not enter any enclosed or confined fire space with out proper protective equipment. This may include self-contained breathing apparatus to protect against the hazardous effects of normal products or combustion or oxygen.

7. Accidental Release Measures

SPILLS: Sweep up spilled materials and dispose of appropriately. It is the user's responsibility to comply with all local, state and federal laws, rules, regulations and standards.

8. Handling and Storage

To protect quality, avoid excessive heat and store in a tight container in a dry place. Shelf life of product is 2 years from manufacture date.

9. Exposure Controls/Personal Protection

INGESTION: No special precautions.

VENTILATION REQUIREMENTS: No special precautions.

RESPIRATORY PROTECTION: Avoid accidental inhalation.

EYES: Avoid contact with eyes. Wear protective eyeglasses or chemical safety goggles.

SKIN PROTECTION: No special precautions.

10. Physical and Chemical Properties

APPEARANCE: Brown Powder.

ODOR: Characteristic smoky-herbal.

TASTE: Characteristic bitter-herbal

SOLUBILITY IN WATER: $\geq 98\%$.

pH (1% SOLUTION): 3.0 – 5.0

BOILING POINT: TBD

VAPOR PRESSURE: TBD

11. Stability and Reactivity

STABILITY: Stable under ordinary conditions of use and storage.

CONDITIONS TO AVOID: Moisture, Dust and Exposure to Oxygen.

12. Toxicological Information

ACUTE ORAL EFFECTS: Activin Oral LD₅₀ (rat) is >5000 mg solids/kg.

13. Ecological Information

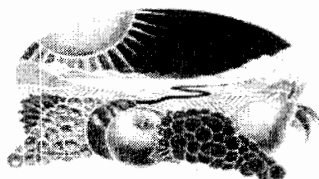
No information found.

14. Disposal Consideration

Dispose of container and unused contents in accordance with federal, state and local requirements.

15. Transport Information

Avoid exposure to temperatures above 120° F (49 °C).



**Providing World-Class, Natural Products
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February 23, 2007

Robert Pooler
Agricultural Marketing Specialist
NOP - USDA
STOP 02068 - Room 4008-5
1400 Independence Avenue
Washington, DC 20250.2000

Dear Mr. Pooler,

Thank you for your letter regarding San Joaquin Valley Concentrates' petition for the addition of Grape Seed Extract onto Section 205.606 of the National Organic Program's (NOP) National List of Allowed and Prohibited Substances (National List).

Please be advised that we are petitioning for the inclusion of Grape Seed Extract, not "Grape Seed Extract Coloring".

In accordance with your letter of January 23, 2007, we have amended section 12(G) of our petition to state; "there are only 2 FDA GRAS approved processors of Grape Seed Extract in the world". Because of the very large volumes of grape seed required and because of the scale of continuous runs required to produce very low yielding quantities of grape seed extract, it is not economically viable and commercially feasible for either of us to produce certified organic Grape Seed Extract.

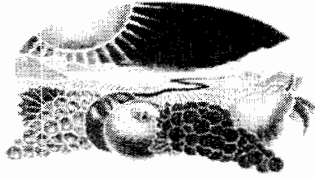
As the petition previously and currently states: "Because of the large volumes of seeds required, the extremely capital intensive nature of the process and very low yields of Grape Seed Extract (100 Parts of Raw to 1 Part of Finished Ingredient), it is not commercially available as organic in accordance with Section 205.606. There are only two sources of FDA approved Grape Seed Extract and neither producer offers certified organic Grape Seed Extract."

The additional factors of weather, trade related and other issues cited in 12(G) are not currently relevant to this petition and are regarded as not applicable (N/A).

The clarifications in this letter should also be considered as an official part of the San Joaquin Valley Concentrates' Section 205.606 petition for the inclusion of Grape Seed Extract on the NOP National List.

Respectfully amended,

Phil Castro
San Joaquin Valley Concentrates
Director of Operations
559-458-2588



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3. The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer or disinfectant:

Grape Seed Extract is a high grade, high solubility, readily dispersible proanthocyanidin. It is a 100% pure grape seed extract for use in foods, beverages, and dietary supplements applications. (Natural Antioxidant)

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Grape Seed Extract is a natural antioxidant that delivers Oligomeric Proanthocyanidins (OPC) to organic "Heart Healthy" food products

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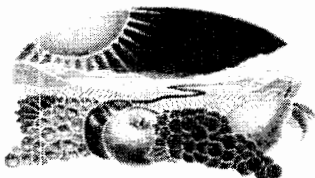
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See attached FDA GRAS GRN 000124

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8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance

N/A. Grape Seed Extract is a natural product.

9. The substance's physical properties and chemical mode of action including (a) chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use or manufacture; (d) effects on human health; and, (e) effects on soil organisms, crops, or livestock :

See attached FDA GRN 000124

10. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies:

See attached MSDS

11. Research information about the substance, which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List.

See Attached MSDS FDA GRN 000124

12. "Petition Justification Statement"

GRAPE SEED EXTRACT

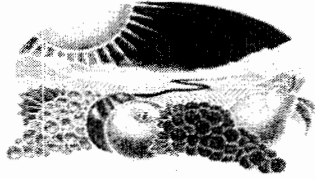
Grape Seed Extract is an essential Oxygen Radical Absorption Capacity (ORAC) ingredient in "heart healthy" natural products. Grape Seed Extract is a natural source of Oligomeric Proanthocyanidins (OPC). Grape Seed Extract contains the highest ORAC values. It is they most concentrated source of antioxidants and is, by far, the highest source of Oligomeric Proanthocyanidins (OPC) in other sources that include wine , rapeseed oil, grapes, blueberries and cranberries. Grape Seed Extract is important to the organic processing industry because it does not impart an off flavor to the finished product. There are only two suppliers of GRAS (General Recognized as Safe) Grape Seed Extract that are allowed to be used in a Food and Beverage application. The volumes produced from these GRAS approved Grape seed extract is limited and can not be supplemented with NON-GRAS grape seed extract.

Handling practices used in the production of Grape Seed Extract are compatible with Section 205.207

There are no known global sources of organic grape seed extract. Because of the large volumes of seeds required, extremely capital intensive processes and very low yields (100 units of raw material to 1 unit of finished product) of Grape Seed Extract, it is not commercially available in accordance with Section 205.606.

Grape Seed extract is an important environmental use of grape seeds that historically have been considered processing waste. The production of grape seed extract adds economic value to a previously discarded post-processing product.

13. San Joaquin Valley Concentrates has attached a Confidential Business Information Flow Chart and Proprietary Processing narrative. These documents are marked "CBI COPY"



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EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 2. Is the Substance Essential for Organic Production?

Substance **ActiVin Grape Seed Extract**

Documentation

1. Is there a natural source of the substance? [§205.600 b.1]

Grape Seed Extract is a natural source

2. Is there an organic substitute? [§205.600 b.1]

NO Grape Seed Extract is a natural source, and is not commercially available from organic sources

3. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]

Grape Seed Extract is an essential in Oxygen Radical Absorption Capacity (ORAC)) ingredient in "heart healthy products.

4. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]

Grape Seed Extract is a Natural Product

5. Is the substance used in handling, not synthetic, but not organically produced?

[§6517 c (1)(B)(iii)]

YES

6. Is there any alternative substances? [§6518 m.6]

Grape Seed Extract is the highest in ORAC values and is important to the organic processing industry because it does not impart an off flavor to the finished product. It is they most concentrated source of antioxidants and is, by far, the highest source of Oligomeric Proanthocyanidins (OPC) in other sources that include wine , rapeseed oil, grapes, blueberries and cranberries.

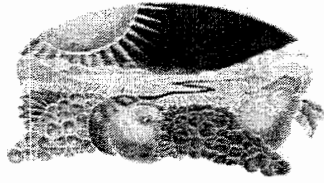
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]

NO, there are no other natural product available to compare to the concentrated OPC levels of Grape Seed Extract

SAN JOAQUIN VALLEY CONCENTRATES

Activin Grape Seed Extract
Process Flow

Confidential
Business
Information
January 2007



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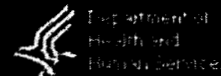
Description of Process Flow Chart for ActiVin Grape Seed Extract

Confidential Business Information (CBI) January 2007

SAN JOAQUIN VALLEY CONCENTRATES, 5631 E. OLIVE AVE., FRESNO, CA 93727
TOLL FREE: (800) 557-0220 OFFICE: (559) 458-2500 FAX: (559) 458-2564



U.S. Food and Drug Administration



CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

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CFSAN/Office of Food Additive Safety
August 1, 2003

Agency Response Letter GRAS Notice No. GRN 000124

Mr. Steven J. Anderson
Vice President
San Joaquin Valley Concentrates
5631 East Olive Avenue
Fresno, CA 93727

Re: GRAS Notice No. GRN 000124

Dear Mr. Anderson:

The Food and Drug Administration (FDA) is responding to the notice, dated January 28, 2003, that you submitted in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received the notice on February 3, 2003, filed it on February 14, 2003, and designated it as GRAS Notice No. GRN 000124.

The subject of the notice is grape seed extract (GSE). The notice informs FDA of the view of San Joaquin Valley Concentrates (San Joaquin) that GSE is GRAS, through scientific procedures, for use in beverages and beverage bases, breakfast cereals, fats and oils, frozen dairy desserts and mixes, grain products, milk (whole and skim), milk products, processed fruits and fruit juices at levels ranging from 0.01 to 0.08 percent. In oil/water systems, GSE functions as an antioxidant and as an emulsifier; in aqueous solutions, GSE functions as an antioxidant. San Joaquin notes that the astringent flavor that is associated with use levels greater than 0.05 percent makes the use of GSE self-limiting.

As part of its notice, San Joaquin includes the report of a panel of individuals (San Joaquin's GRAS panel) who evaluated the data and information that are the basis for San Joaquin's GRAS determination. San Joaquin considers the members of its GRAS panel to be qualified by scientific training and experience to evaluate the safety of substances added to food. San Joaquin's GRAS panel evaluated estimates of dietary exposure, method of manufacture, and product specifications as well as published studies on San Joaquin's GSE and other grape seed extract products or components. Based on this review, San Joaquin's GRAS panel concluded that GSE, meeting food grade specifications and produced in compliance with good manufacturing practice, is GRAS,

through scientific procedures, as an antioxidant and/or emulsifier in conventional foods under the conditions of its intended use.

San Joaquin describes GSE as a soluble, rose-brown powder that is a complex mixture of polyphenolic compounds, trace amounts of lipids and protein and small amounts of polysaccharides. Polyphenols are commonly found in higher plants, and are a diverse group of polymeric compounds containing multiple phenolic functionalities. Polyphenols are classified according to their repeating monomeric building blocks. In GSE, these monomers generally fall into two classes, i.e., flavonoids and non-flavonoids. The flavonoid polymers that are known as proanthocyanidins contain a specific type of flavonoid (called flavanols) as monomers. The non-flavonoid polymers are composed of esters of the monomers gallic acid or hexahydroxydiphenyl and a polyol (such as D-glucose). Other non-flavonoid polyphenols can be found in GSE and are composed of the monomers caffeic acid, chlorogenic acid and resveratrol.

San Joaquin notes that GSE is composed of approximately 74 to 78 percent proanthocyanidins and less than approximately 6 percent of free flavanol monomers on a dry weight basis. Specifically, San Joaquin states that GSE contains the flavanol monomers (+)-catechin, (-)-epicatechin, (-)-epicatechin gallate (ECG), (-)-epigallocatechin (EGC), and (-)-epigallocatechin gallate (EGCG).

San Joaquin describes the method of manufacture for GSE. Seeds obtained from grapes (*Vitis vinifera*) are purified, dried, and extracted with deionized water under heat and increased pressure. The aqueous extract is ultrafiltered to remove suspended solids and applied to a chromatographic column that adsorbs the proanthocyanidins. The adsorbed proanthocyanidins are eluted from the column with ethanol and then concentrated by nanofiltration and/or evaporation. The concentrated proanthocyanidin extract is dried to remove residual water and ethanol, ground to particle-sized specifications, blended, and packaged. San Joaquin reports that all materials involved in the manufacturing process are appropriate for food use. San Joaquin provides product specifications for GSE. Specifications include limits on the maximum levels of total phenols (gallic acid equivalents), total monomers, loss on drying, protein, ash, fat, polysaccharides, heavy metals, and microbial contaminants.

Using the United States Department of Agriculture 1994-1996 Continuing Surveys of Food Intakes by Individuals and the 1998 Supplemental Children's Survey, San Joaquin estimates the intake of GSE for the total population from San Joaquin's intended use of GSE would be approximately 150 milligrams per person per day (mg/person/day) at the mean (equivalent to approximately 3 milligrams per kilogram body weight per day (mg/kg body weight/day)) and approximately 300 mg/person/day at the 90th percentile (equivalent to approximately 6 mg/kg body weight/day). San Joaquin also estimates that the current per capita consumption of total proanthocyanidins and total flavanol monomers (from foods including tea, wine, beer, fruits and fruit juices, and chocolate) is approximately 500 mg/person/day and approximately 220 mg/person/day, respectively. San Joaquin concludes that the estimated intake of GSE would be similar to or less than the current dietary intake of total proanthocyanidins and total flavanol monomers from their natural occurrence in food.

San Joaquin discusses published information related to the absorption, distribution, metabolism, and excretion of proanthocyanidins. Although intact proanthocyanidins are poorly absorbed across the intestinal lumen, they may be hydrolyzed in the upper intestinal tract or degraded by intestinal microflora. When proanthocyanidins are absorbed, they and their metabolites are transported to the liver and other organs (e.g., kidney, lung, spleen, and connective tissue) where they are further metabolized and subsequently eliminated via urine, feces, biliary excretion, and respiration.

San Joaquin discusses published studies conducted with San Joaquin's GSE and other grape seed extract products or components in humans and various animal species and draws the following conclusions:

- Acute, subchronic and chronic oral toxicity studies conducted in animals fed GSE, other grape seed extracts, or substances that are components of GSE showed no relevant compound-related toxicological effects.
- Genotoxicity studies conducted in vivo or in vitro with commercial grape seed extracts or substances that are components of GSE demonstrated no mutagenic effects.
- Reproductive and developmental toxicity studies conducted in animals fed (+)-catechin demonstrated no adverse effects.
- Clinical, epidemiological and nutritional studies conducted with substances that are components of GSE demonstrated no significant adverse effects.

San Joaquin reports that GSE was evaluated by the Flavor and Extract Manufacturer's Association and was found to be acceptable for use as a flavoring agent at levels of 100 to 200 parts per million in fruit based beverages, powdered drink mixes, salad dressings, frozen desserts, cultured dairy products and skimmed milk.

Potential labeling issues

Section 403(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA) provides that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. Section 403(i)(2) of the FFDCA provides that a food shall be deemed to be misbranded unless its label bears the common or usual name of each ingredient. In addition, section 403(k) of the FFDCA provides that a food shall be deemed to be misbranded if it bears or contains any chemical preservative, unless it bears labeling stating that fact. San Joaquin's use of GSE as an antioxidant constitutes use as a preservative. Therefore, the ingredient statement on labels of food products treated with GSE must comply with 21 CFR 101.22(j), which requires a food to which a chemical preservative is added to bear a label declaration stating both the common or usual name of the ingredient and a separate description of its function. If you have any questions about the appropriate labeling of this food ingredient, you should contact the staff in the Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS), Division of Food Labeling and Standards, 5100 Paint Branch Parkway, College Park, MD 20740. You can also reach this division by telephone at (301)436-2375.

In addition, Section 403(r) of the FFDCA lays out the statutory framework for a health claim. In describing the intended use of GSE and in describing the information that San Joaquin relies on to conclude that GSE is GRAS under the conditions of its intended use, San Joaquin raises potential labeling issues under these provisions of the FFDCA. These labeling issues consist of San Joaquin's assertion that GSE has physiological effects that San Joaquin views as beneficial. If products that contain GSE bear any claims about such benefits on the label or in labeling, such claims are the purview of ONPLDS. The Office of Food Additive Safety (OFAS) neither consulted with ONPLDS on these labeling issues nor evaluated the information in San Joaquin's notice to determine whether it would support any claims made about GSE on the label or in labeling.

Standards of identity

In its notice, San Joaquin states its intention to use GSE in several food categories, including foods for which standards of identity exist, located in Title 21 of the Code of Federal Regulations. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity. If you have any questions about the use of GSE in standardized foods that would

be marketed in the United States, you should contact the staff in ONPLDS, Division of Food Labeling and Standards

Conclusions

Based on the information provided by San Joaquin, as well as other information available to FDA, the agency has no questions at this time regarding San Joaquin's conclusion that GSE is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of GSE. As always, it is the continuing responsibility of San Joaquin to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter, as well as a copy of the information in your notice that conforms to the information in proposed 21 CFR 170.36(c)(1), is available for public review and copying on the homepage of the Office of Food Additive Safety (on the Internet at <http://www.cfsan.fda.gov/~lrd/foodadd.html>).

Sincerely,

/s/

Laura M. Tarantino, Ph.D.
Acting Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

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FDA/Center for Food Safety & Applied Nutrition
Hypertext updated by [amp/rxm/iah/pmg](#) September 22, 2003

MSDS Material Safety Data Sheet

San Joaquin Valley Concentrates
5631 E. Olive Ave.
Fresno, CA 93727 USA
559-458-2500

ActiVin Grape Seed Extract

1. Product Identification

Appearance: Dark Brown Powder
Classification: Organic, Nutritive
Description: Proanthocyanidin Grape Seed (*Vitis vinifera*) Extract
Trade Name: Activin™
Product Code: GSE, GSE-HD
Order Code: FG13000
Research Code: IH636

2. Composition/Information on Ingredients

Phenols (Gallic Acid Equivalents) of Solids 80 – 95%

3. Hazards Identification

None.

4. Potential Health Effects

INGESTION: Activin Oral LD₅₀ (rat) is >5000 mg solids/kg.

INHALATION: May cause irritation of mucous membranes.

SKIN CONTACT: No known risk.

EYE CONTACT: Direct contact can cause irritation of the conjunctiva, cornea and iris.

5. First Aid Measures

INGESTION: Drink plenty of water. If any discomfort persists, obtain medical attention.

INHALATION: Remove victim to fresh air. If breathing is difficult or if any discomfort persists, obtain medical attention.

SKIN CONTACT: Wash with soap and water.

EYE CONTACT: Flush with clean water. If irritation persists obtain medical attention.

6. Fire Fighting Measures

FIRE AND EXPLOSION HAZARD: None.

HAZARDOUS DECOMPOSITION PRODUCTS: None known.

STABILITY: Stable.

FLASH POINT: Not applicable

FLAMMABLE LIMITS (Air): Not applicable

EXTINGUISHING MEDIA: WATER

FIRE FIGHTING PROCEDURES: For fires involving this material, do not enter any enclosed or confined fire space with out proper protective equipment. This may include self-contained breathing apparatus to protect against the hazardous effects of normal products or combustion or oxygen.

7. Accidental Release Measures

SPILLS: Sweep up spilled materials and dispose of appropriately. It is the user's responsibility to comply with all local, state and federal laws, rules, regulations and standards.

8. Handling and Storage

To protect quality, avoid excessive heat and store in a tight container in a dry place. Shelf life of product is 2 years from manufacture date.

9. Exposure Controls/Personal Protection

INGESTION: No special precautions.
VENTILATION REQUIREMENTS: No special precautions.
RESPIRATORY PROTECTION: Avoid accidental inhalation.
EYES: Avoid contact with eyes. Wear protective eyeglasses or chemical safety goggles.
SKIN PROTECTION: No special precautions.

10. Physical and Chemical Properties

APPEARANCE: Brown Powder.
ODOR: Characteristic smoky-herbal.
TASTE: Characteristic bitter-herbal.
SOLUBILITY IN WATER: ≥98%.
pH (1% SOLUTION): 3.0 - 5.0
BOILING POINT: TBD
VAPOR PRESSURE: TBD

11. Stability and Reactivity

STABILITY: Stable under ordinary conditions of use and storage.
CONDITIONS TO AVOID: Moisture, Dust and Exposure to Oxygen.

12. Toxicological Information

ACUTE ORAL EFFECTS: Activin Oral LD₅₀ (rat) is >5000 mg solids/kg.

13. Ecological Information

No information found.

14. Disposal Consideration

Dispose of container and unused contents in accordance with federal, state and local requirements.

15. Transport Information

Avoid exposure to temperatures above 120° F (49 °C).