colorMaker®

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January 15,, 2007

ORIGINAL

Robert L. Pooler
National Organic Program, AMS / USDA
STOP 0268 – Room 4008S
1400 Independence Avenue SW
Washington, DC 20250-0268

Re: Petitions for the Addition of
Non-Organic Agricultural Substances to the National List
Pursuant to Section 205.606 of the NOP

Dear Mr. Pooler:

Thank you for your letter, dated December 20, 2006, wherein you returned our original "combined" petition for fifteen natural colorants (dated October 16, 2006) and instructed us to file fifteen "separate" petitions, one for each colorant.

Pursuant to your instructions, please find enclosed with this letter fifteen (15) separate petitions, one for each natural colorant. We enclose an original and one copy of each petition for you to review. We ask the National Organic Standards Board (NOSB) to add onto the National List the following natural colorants:

Anthocyanins: (1) chokeberry juice, (2) black currant juice, (3) red cabbage extract, (4) purple carrot extract, (5) elderberry juice, (6) grape juice, (7) grape skin extract, (8) red radish extract; and

Carotenoids: (9) annatto seed extract, (10) beta-carotene from carrots, (11) lycopene, (12) paprika, (13) saffron; and

Betalains: (14) beet juice; and

Other: (15) turmeric.

You may recall that our original petition was organized by the four categories shown above. It may be prudent -- in the interest of time -- for the NOSB to consider the enclosed petitions in these same categories / groups.

DDWilliamson
Color With Confidence

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Petition for the Addition of
A Non-Organic Agricultural Substance to the National List
Pursuant to Section 205.606 of the NOP

1. The substance's common name: Grape skin extract, the extract from the skins of *Vitaceae vitis vinifera* (family, genus, species). This agricultural substance is also commonly mistaken for "grape juice."

2. The producer's name, address and telephone number: There are limited numbers of producers of grape skin extract, among them are:

2.1 Canandaigua / Centerra Wine Co.
116 Buffalo Street
Canandaigua, NY 14424
United States
(888) 659-7900

2.2 Diana Naturals
707 Executive Drive
Valley Cottage, NY 10989
United States
(845) 268-5200

3. The intended or current use of the substance: Grape skin extract is used as a natural color additive in baked goods, beverages, candies & gums, condiments, dairy products, desserts, jams & gelatins, pet foods, snack foods, soups & sauces, and compressed tablets. Its usage as a color additive exempt from certification is permitted by the US Food & Drug Administration (the "FDA") under 21 CFR 73.

The use of grape skin extract as a natural color additive supports and promotes the organic philosophy because an all-natural, agricultural product is being used to improve the visual appeal of organic food and beverage products, rather than artificial colors such as FD&C Red 40. Thus, grape skin extract may advance the organic movement by helping organic producers present to consumers a wide variety of organic food and beverage products with dynamic visual appeal.

4. A list of handling activities for which the substance will be used: Grape skin extract develops a deep blue to bright red color in organic food and beverage products, depending upon the pH of the finished product. It is used as a natural color additive to enhance the visual appeal of organic products. The color, itself, results from high concentrations of anthocyanin molecules in the skins.

5. The source of the substance and a detailed description of its manufacturing or processing procedures: Grapes grow on vines throughout the entire world. The grape skins are collected, washed, and crushed into small pieces. Pieces are soaked in water. After 42 – 78 hours, the liquid is mechanically filtered and concentrated, producing a dark, blue-red liquid concentrate composed of the same anthocyanin molecules produced inside the skins.

6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance: Countless government reviews of grape skin extract are known. Anthocyanins from grape skins have been used since antiquity to color human foods and are Generally Regarded As Safe (GRAS). Grape skin extract is one of the oldest known "processed" foods.

7. Information regarding EPA, FDA, and State Regulations: FDA permits the use of grape skin extract as a color additive exempt from certification. 21 CFR 73.250 Fruit Juice. Grape skin extract is also permitted as a natural color additive in foods in the European Union (E163) and throughout Asia.

8. The Chemical Abstract Service (CAS) number: There is no specific CAS Number for grape skin extract; however, anthocyanins in general have been assigned CAS No. 11029-12-2.

9. The substance's physical properties and chemical mode of action: The anthocyanins extracted from grape skins are distinct and unique molecules. They are different from carotenoids and betalains (other molecules used as natural colorants). Anthocyanins are sensitive to the pH of their surrounding environment, appearing red in an acidic pH (pH < 4.5.) and blue in an alkaline pH (pH > 6.5). In addition, anthocyanins display strong antioxidant properties which may be beneficial to human health. Beyond these unique properties, anthocyanins do not interact with substances used in organic food production and have no impact on the environment.

Grape skins have been consumed for centuries and their growth and ultimate consumption has the exact same impact on the environment as organically grown, biodegradable fruits and vegetables.

10. Safety information about the substance: Please see the attached Material Safety Data Sheet (MSDS). Grape skins, and the anthocyanins extracted from grape skins, are GRAS.

11. Research information about the substance: See the attached Bibliography. A leading American researcher on anthocyanins is Professor Ron Wrolstad, Dept. of Food Science, University of Oregon, Corvallis, OR 97331. Dr. Worlstad recently retired, but he can still be reached at the University.

12(G) Justification Statements:

Enhanced Visual Appeal Using Natural Colorants. Food safety dictates that processed foods must be fully cooked to assure low bacterial counts for extended shelf-life and broad geographical distribution. Many food and beverage processors also employ a low pH environment and/or low water activity and/or or low temperature distribution of the finished product (refrigeration or freezing) to further assure minimal bacterial counts. These processing parameters are challenging to colorants residing inside the "core food" (for example, chlorophyll inside florets of broccoli, beta-carotene inside cut carrots, or anthocyanins inside strawberry preserves).

The addition of natural colorants compensates for the "original" colorants destroyed by high temperature / low pH processing. In so doing, the finished organic food or beverage product presents to the consumer the same visual appeal it would have if it were fresh. The addition of natural colorants can also enhance an existing color, making the organic food or beverage even more appealing; or it may extend the shelf-life of an organic food or beverage, making it available to more consumers both over time and geographical distance.

Without the addition of natural colorants, organic food and beverage products might lack the visual appeal and attraction of their direct non-organic competition. Thus, natural colorants help organic processors compete.

In so doing, natural colorants advance the organic philosophy by (literally) displaying to consumers visually appealing organic food and beverage products brightly colored without artificial colors such as FD&C Yellow 5.

Low Usage Levels of Natural Colorants. Because natural colorants are concentrated and very strong, they are used in organic food and beverage products at very low levels, typically less than 1%. The inherent strength of natural colorants sets in motion or "triggers" two distinct events: (1) natural colorants always fall under the 95 / 5 rule where five percent of the ingredients in an organic product may be non-certified; and (2) the volume of natural colorants purchased is very small.

By way of example, a hypothetical organic dairy develops organic certified yogurt. First, new product developers add grape skin extract at 0.5% of the formula. They do not actively seek out organic certified grape skin extract because they know the ingredient easily falls under the 95 / 5 rule. Second, the dairy's new product is successful and within the first year it produces 500 tons of organic certified yogurts. Despite such success, the dairy would purchase only 833 lb of grape skin extract per month. This low volume of natural colorant sales, combined with inclusion of natural colorants in the "five percent non-certified" portion of the formula, provides little economic incentive to certify natural colorants as organic.

In the future, we anticipate the total amount of organic food and beverage products to increase. We may reach a point in time where a strong economic incentive places natural colorant crops under organic systems of production. It should be noted that no ingredient may remain on the National List for more than five (5) years without review by the National Organic Standards Board (NOSB).

The NOSB must therefore review the status of natural colorants five years hence (roughly 2012) and, at that time, may discover that an adequate supply of natural colorants is available for use in organic foods and beverages.

International Production of Natural Colorants. Most natural colorants are derived from International fruit and vegetable crops grown in developing countries; there is little International acreage certified organic. Most international organic acreage is utilized for corn, sugar and grains. Further, organic certification of International acreage remains problematic, plagued by cultural, financial, and language difficulties. Moreover, most fruit and vegetable crops are typically consumed where they are grown. As a result, there is a limited supply of the requisite fruit and vegetable crops needed for the creation of natural colorants.

Thus, natural colorants are not available in the appropriate quantity from International sources to meet the needs of organic processors.

Domestic Production of Natural Colorants / The Current State of the US Organic Industry. Certified organic cropland and pasture accounted for about 0.5% of total US farmland in 2005. Only a small percentage of top US field crops – corn (0.2%), soybeans (0.2%), and wheat (0.5%) – were grown under certified organic farming systems. Organic carrots (6% of the US carrot acreage), organic lettuce (4% of US lettuce acreage), and organic apples (3% of US apple acreage) were more commonly grown organic.

Markets for organically grown fruits and vegetables have been developing for decades in the US, and fresh produce is still the top-selling organic category in retail sales. Organic livestock was beginning to catch up with produce in 2005, with 1% of US dairy cows and 0.6% of the layer hens managed under certified organic systems. After decades of strong growth, the US organic marketplace is a bountiful "Farmers' Market" for consumers, but it does not supply the appropriate quantity of natural colorants for organic food processors.

Because there is no current supply of organic certified natural colorants from International sources, and because there is no current supply of organic certified natural colorants from US sources, and because natural colorants at levels below 5% greatly improve the visual appearance of organic foods and beverages, this Petition seeks the addition of natural colorants to the National List.

13. This Petition respectfully seeks the addition of grape skin extract, not to be mistaken for "grape juice," to the National List as a non-organic agricultural product under Section 205.606 of the NOP.

Respectfully Submitted,

COLORMAKER, INC.,
a California corporation

By: _____
Stephen J. Lapo
(Name & Title)

DD WILLIAMSON, INC.
a Kentucky corporation

By: Margaret A. Lawson
Margaret A. Lawson
(Name & Title)
VP Science & Innovation

ColorMaker, Inc.
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Hazard rating at a glance
0-least, 1-slight, 2-moderate, 3-high, 4-extreme

HEALTH	0
FLAMMABILITY	0
REACTIVITY	0

MATERIAL SAFETY DATA SHEET

1. *Product Identification:*

1.1 Product Name: Standard Grape Skin Extract

1.2 Product Number: 2728B

1.3 Ingredient Statement: Grape skin extract

1.4 Description of Product: A purple liquid designed to color and function in food and beverage products. Specific formulation is withheld as a trade secret pursuant to 21 CFR 20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21 CFR 73. None of the ingredients appear on the list of hazardous items established under California's Proposition 65.

2. *Hazardous Ingredients and Exposure Limits:*

2.1 It is our opinion that the above named product does not meet the definition of a "Hazardous Chemical" as defined in 21 CFR 1910.1200. This MSDS is provided as general information for health and safety reasons.

3. *Health Hazard Data*

3.1	Carcinogenic	None known.
3.2	Acute Toxicity	None known.
3.3	Oral LD50	Not determined.
3.4	Dermal LD50	Not determined.
3.5	Ingestion	None known.
3.6	Skin Contact	None known.
3.7	Irritation (skin)	None known.
3.8	Irritation (eye)	May cause slight irritation.

4. *First Aid Measures*

4.1	Eye Contact	Remove contact lenses and flush eyes with copious amount of water for at least fifteen minutes. Contact physician if irritation persists.
4.2	Skin Contact	No significant health hazard. Wash exposed skin with soap and water for at least fifteen minutes. If irritation persists, consult a doctor.
4.3	Ingestion	Administer 1 - 2 glasses of water or milk to dilute. DO NOT INDUCE VOMITING. Seek medical attention if it seems advisable.

5. *Fire Fighting Measures*

5.1	Flash Point (method used)	Not determined.
5.2	Flammable Limits	Not determined.
5.3	Unusual Fire & Explosion Hazard	None known.
5.4	Extinguishing Media	Carbon dioxide, dry chemical, foam, and water spray.

6. *Spill, Leak, and Waste Disposal*

6.1 Absorb spills on vermiculite or other absorbent materials. Remove to approved disposal containers. Use rag and mop to clean small spots or dilute with large amounts of water. Colorant is biodegradable.

7. *Handling and Storage*

7.1 Store in a cool dry area. The wearing of rubber gloves and safety glasses to prevent skin and eye contact is recommended. Store in tightly closed containers.

8. *Exposure Protection*

8.1	Respiratory	No special equipment under normal conditions of use.
8.2	Skin	Skin protection appropriate to use conditions.
8.3	Eye	Safety glasses must be worn at all times
8.4	Hand	Suitable gloves.
8.5	Other	None

9. *Physical / Chemical Characteristics*

9.1	Appearance	Purple liquid
9.2	Boiling Point	Not established
9.3	Vapor Pressure	Not established
9.4	pH value	7.0
9.5	Solubility in Water	Complete
9.6	Specific Gravity	To be established

10. *Stability and Reactivity*

10.1	Stability	Stable.
10.2	Incompatibility	Avoid strong oxidizing agents.
10.3	Hazardous Decomposition	Not known.
10.4	Hazardous Polymerization	Not known.

11. *Toxicological Health Hazards*

11.1 None known. Colorant is naturally derived and biodegradable.

12. *Ecological Effects*

12.1 None known. Colorant is naturally derived and biodegradable

13. *Disposal Considerations*

13.1 Incineration. Observe local, State, and Federal regulations concerning health and the environment. Do not incinerate in sealed containers.

The information contained herein is based upon data considered accurate and reliable. Nevertheless, an independent investigation and verification of this information should be made by the user. No warranty is made, expressed or implied, regarding the accuracy or correctness of these data. The use of this information and this product are beyond the control of ColorMaker, Inc. Therefore, it is the sole responsibility of the user to determine the conditions necessary for the safe use of this product.

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EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance – GRAPE SKIN EXTRACT

Question	Yes	No	N/A	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		X		Petition; FDA regulations
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		Petition; FDA regulations
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Petition; FDA Regulations
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			X	
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		Petition; FDA Regulations
6. Are there adverse biological and chemical interactions in agroecosystem? [§6518 m.5]		X		Petition; FDA Regulations
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		Petition; FDA Regulations
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]			X	
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		Petition; FDA Regulations
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		Petition; FDA Regulations
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		Petition; FDA Regulations

12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			Petition; FDA Regulations
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		Petition; FDA Regulations

1 If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 2. Is the Substance Essential for Organic Production? Substance – GRAPE SKIN EXTRACT

Question	Yes	No	N/A	Documentation (TAP; petition; regulatory agency; other)
1. Is there a natural source of the substance? [§205.600 b.1]			X	
2. Is there an organic substitute? [§205.600 b.1]		X		Petition
3. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
4. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			X	
5. Is the substance used in handling not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			Petition; FDA Regulations
6. Is there any alternative substances? [§6518 m.6]		X		Petition; FDA Regulations
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]			X	

1 If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 3. Is the substance compatible with organic production? Substance – GRAPE SKIN EXTRACT

Question	Yes	No	N/A	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			X	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X			Petition; FDA Regulations
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			Petition; FDA Regulations
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]		X		
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]			X	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:				
a. copper and sulfur compounds;			X	
b. toxins derived from bacteria;			X	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	
d. livestock parasiticides and medicines?			X	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	

1 If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

CBI Deleted Version

Petition to the National Organic Standards Board and the National Organic Program for the Addition of Grape Skin Extract to the National List Section §205.606

Item A

This is a petition to amend the National List Section §205.606 to include Grape Skin Extract as a non-organically produced agricultural product allowed as an ingredient in or on processed products labeled as "organic".

Item B

1. Substance Common Name.

Grape Skin Extract is the common name for the coloring components extracted from the scientific varieties of *Vitaceae vitis vinifera.*

2. Manufacturers' Names, Addresses, and Telephone Numbers.

This petition is submitted by the International Association of Color Manufacturers' on behalf of our members.

International Association of Color Manufacturers'
1620 I Street NW, Suite 925
Washington, DC 20006
Phone: (202) 293-5800
Fax: (202) 463-8998

Contact: Sean Taylor, IACM Scientific Director
E-mail: staylor@therobertsgroup.net

Relevant member companies include (but are not limited to):

D.D. Williamson & Co., Inc.
1901 Payne Street
Louisville, KY 40206
USA

Wild Flavors, Inc.
1261 Pacific Avenue
Erlanger, KY 41018
USA

Chr. Hansen, Inc.
9015 West Maple Street
Milwaukee, WI 53214
USA

3. Intended or current use of the substance.

Grape Skin Extract is a highly colored fruit juice that has applications in food as a coloring substance. It is primarily used to color a variety of organic and non-organic still and carbonated drinks and ades,

beverage bases and alcoholic beverages. Grape Skin Extract adds a pink to deep purple color to these beverages, depending upon the exact concentration used. Grape Skin Extract is generally used at a very low level in foods, with typical concentrations of 0.05-0.1% in the final food product. As is described in 21 CFR 73.250, Grape Skin Extract is approved by the Food and Drug Administration (FDA) for use at all concentrations that are considered Good Manufacturing Practices and that do not exceed those levels necessary to provide the intended coloring effect.

Grape Skin Extract is currently used as a color additive in a variety of organic and non-organic food products. In organic foods, Grape Skin Extract has been in use as an allowed non-synthetic ingredient under "Colors, non-synthetic sources only," which is listed on the National List §205.605(a). However, the National Organic Standards Board has recommended that "Colors, non-synthetic sources only" be allowed to sunset off of the National List in October 2007. Therefore, Grape Skin Extract must be added as an individual coloring substance onto the National List. Due to the minimal processing involved in its production, Grape Skin Extract meets the current definition of an agricultural substance. This petition is to place Grape Skin Extract as an allowed non-organic agricultural ingredient under §205.606 until such an organic form of Grape Skin Extract is commercially available to organic foods producers in the necessary form, quality and quantity that is needed to fulfill the demands of the organic industry.

4. List of crop, livestock, or handling activities for which the substance will be used. If used for handling (including processing), the substance's mode of action must be described.

Grape Skin Extract is used in handling only for food application as described above. The water-soluble extract is commonly added during formulation of the food product and it mixes homogenously with the aqueous phase. Grape Skin Extract acts to supplement the inherent natural color found in the aqueous phase of the food product formulation. This natural color is often partially or completely lost during heating steps involved in the processing. As is described above, Grape Skin Extract is used at very low levels in food products, and it therefore is not known to impart any other technical effect in the food product.

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. Petitioners with concerns for confidential business information can follow the guidelines in the Instructions for Submitting Confidential Business Information (CBI) listed in #13.

Grape Skin Extract is the extract used as a coloring material that is produced from the common grape, *Vitaceae vitis vinifera*. In production of the extract, grapes are harvested from grapevines when

CBI Deleted—processing information

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CBI Deleted

CBI Deleted—processing information

CBI

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

To the best of our knowledge, no previous reviews have been conducted to approve the use of Grape Skin Extract used as a food coloring material as a nonorganically-produced agricultural ingredient in or on foods labeled as 'organic' or 'made with organic'. Currently, all food coloring substances that are non-synthetic are on the National List, Section 205.605(a), under "Colors, Non-Synthetic Sources Only" (the NOSB was provided with a technical advisory panel review of "Colors, Non-Synthetic Sources Only" that was completed in October 2005. It is included as Attachment #1 to this petition). However, the National Organic Standards Board has recommended that 'Colors, Non-Synthetic Sources Only' not be renewed to the National List, and it is therefore scheduled to sunset from the National List effective October 22, 2007. Given this regulatory history, no state or private certification programs are known to have conducted reviews of Grape Skin Extract.

Information about Grape Skin Extract or other forms of grape products sold as organic will be found in this petition. Please see Item B Nos. 11 & 12, Petition Justification Statement.

While to the best of our knowledge no other reviews have been Grape Skin Extract, reviews of anthocyanins, the predominant coloring components in Grape Juice, have been done. They include the Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The evaluation of anthocyanins may be found at: http://www.inchem.org/documents/jecfa/jecmono/v17je05.htm and is included here as Attachment #2.

The Canadian Organic Standards, that were published September 2, 2006, include colors for use in food products under the following listing: §5.4.2.1 Colouring, natural, from non-synthetic sources only and shall not be produced using synthetic solvents and carrier systems or any artificial preservative.

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

Grape Skin Extract conforms in every aspect to the requirements mandated by the Federal Food, Drug, and Cosmetic Act. Grape Skin Extract used as a coloring material is fully consistent with 21 CFR 73.250:

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Sec. 73.250  Fruit juice.
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> (a) Identity. (1) The color additive fruit juice is prepared either by expressing the juice from mature varieties of fresh, edible fruits, or by the water infusion of the dried fruit. The color additive may be concentrated or dried. The definition of fruit juice in this paragraph is for the purpose of identity as a color additive only and shall not be construed as a standard of identity under section 401 of the act. However, where a standard of identity for a particular fruit juice has been promulgated under section 401 of the act, it shall conform to such standard.
>
> (2) Color additive mixtures made with fruit juice may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.
>
> (b) Uses and restrictions. Fruit juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.
>
> (c) Labeling. The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of Sec. 70.25 of this chapter.
>
> (d) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

No listing for Grape Skin Extract was found in the Environmental Protection Agency's (EPA) Substance Registry System (SRS).

Like all coloring materials, Grape Skin Extract cannot obtain Generally Regarded as Safe (GRAS) status for its use as a color additive, and obtaining GRAS status for use as a color additive is not necessary. As is detailed in the Frequently Asked Questions (FAQ) section of the FDA's GRAS guidance website (http://www.cfsan.fda.gov/~dms/grasguid.html#Q6):

> Is a substance that is used to impart color eligible for classification as GRAS?
>
> The short answer is "No." Under section 201(s) of the Act, the GRAS provision applies to the definition of a food additive. There is no corresponding provision in the definition (in section 201(t) of the Act) of a color additive.
>
> However, under section 201(t)(1) and 21 CFR 70.3(f), the term color additive means a material that is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived from a vegetable, animal, mineral, or other source, and that is capable (alone or through reaction with another substance) of

> imparting color when added or applied to a food; except that such term does not include any material which FDA, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring. Under 21 CFR 70.3(g), a material that otherwise meets the definition of color additive can be exempt from that definition on the basis that it is used or intended to be used solely for a purpose or purposes other than coloring, as long as the material is used in a way that any color imparted is clearly unimportant insofar as the appearance, value, marketability, or consumer acceptability is concerned. Given the construct of section 201(t)(1) of the Act and 21 CFR 70.3(f) and (g), the use of a substance that is capable of imparting color may constitute use as both a color additive and as a food additive or GRAS substance. For example, beta-carotene is both approved for use as a color additive (21 CFR 73.95) and affirmed as GRAS for use as a nutrient (21 CFR 184.1245); in some food products, beta-carotene may be used for both purposes.

8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance. If the substance does not have an assigned product number, this fact should be reported.

Chemical Abstracts Service (CAS) No.:

528-58-5 (for cyanidin, the predominant anthocyanin coloring component in Grape Skin Extract)
528-53-0 (for delphinidin, an anthocyanin coloring component in Grape Skin Extract)
643-84-5 (for malvidin, an anthocyanin coloring component in Grape Skin Extract)
134-01-0 (for peonidin, an anthocyanin coloring component in Grape Skin Extract)
1429-30-7 (for petunidin, an anthocyanin coloring component in Grape Skin Extract)
134-04-3 E163 (for pelargonidin, an anthocyanin coloring component in Grape Skin Extract)

European Community (EC) No.:

E163 (for anthocyanins)

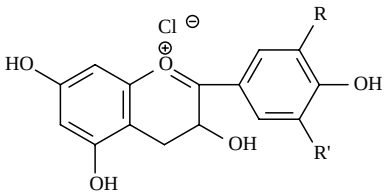
Color Index No.: None found

Please see Attachment #3 for label(s) of products that contain the petitioned substance.

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.

Grape Skin Extract is a red-to-deep purple powder. Although a variety of colored compounds are known to be present, the major coloring principles of Grape Skin Extract are anthocyanins. Grape Skin Extract is soluble in water, and mainly insoluble in oil and ethanol.

Anthocyanins are polyphenolic natural pigments that are widely distributed in the plant kingdom where they occur as glycosides (i.e., associated with a sugar moiety) in combinations that produce orange, red, blue, or purple coloration in a variety of fruits and vegetables. Commercial production of anthocyanins for use as coloring materials began roughly 30 years ago. They are obtained from edible fruits and vegetables, and traditional sources are black currant fruits, elderberry and grapes. The chemical structure of the most commonly occurring anthocyanins that are found in fruits and berries are shown below.



Cyanidin: R=OH, R'=H
Delphinidin: R, R'=OH
Malvidin: R,R'=OCH_3
Pelargonidin: R,R'=H
Peonidin: R=OCH_3, R'=H
Petunidin

Water-soluble anthocyanin pigments such as 3-mono-and 3,5-di-glucosides of malvidin, delphinidin and cyanidin, as well as their acyl ester derivatives, are responsible for the orange, red, blue, and purple colors of anthocyanin-containing fruits. The color intensity increases as pH falls, with stability being greatest below pH 4.5. Fruit extracts that contain anthocyanins are stable to light and temperature, but they are sensitive to oxygen, SO_2 concentration, and the presence of metal ions such as iron, tin, and aluminum which cause them to produce a bluer color (Marmion, 1991).

(a) Chemical interactions with other substances, especially substances used in organic production.

There are no reports of chemical interactions with other substances used in organic production of the food products in which Grape Skin Extract is used as a coloring material.

(b) Toxicity and environmental persistence.

No relevant toxicity or environmental studies for Grape Skin Extract were found. As anthocyanins are the predominant coloring pigments found in Grape Skin Extract, data found for them is summarized below.

Genotoxicity

Anthocyanins are not genotoxic by a weight of evidence analysis (Brown & Dietrich, 1979; Ferguson *et al*., 1985; MacGregor & Jurd, 1978; Viola & Nosotti, 1978; Haveland-Smith, 1981).

Acute Toxicity

The extremely low acute oral toxicity of mixed anthocyanins (cyanidin, delphinidin, petunidin, and malvidin) is demonstrated by mouse and rat LD_{50} values greater than 25 and 20 g/kg bw, respectively (Pourrat *et al*., 1967). Welch's grape color extract administered to rats at 0, 5, 10, 15 and 20% of the diet produced no toxic signs or effects over the 30 day testing period (Stevens and Gallo, 1977).

Long-term Toxicity

No overt signs of toxicity were seen in rats given oral doses of 3000 mg/day mixed anthocyanins for 90 days (Pourrat *et al.*, 1967). No adverse effects occurred when dogs were fed a diet containing 15% grape color powder for 13 weeks (Becci *et al*., 1983a) or grape color extract for 90 consecutive days (Cox and Babish, 1978).

Reproductive/Developmental Toxicity

No adverse effects on reproduction occurred when grape color extract was fed to rats at dietary levels of 7.5 % and 15 % through two generations (Becci *et al*., 1983b; Cox and Babish, 1978). There were no teratogenic effects in multi-generation studies with rats, mice, or rabbits (Pourrat *et al*., 1967).

Metabolism

Anthocyanins are not readily absorbed from the intestine and the small quantity absorbed appears to be excreted by the kidney in its unchanged form (Horwitt, 1933).

Environmental persistence

There is no evidence of environmental persistence from the production of Grape Skin Extract or anthocyanins used as a coloring material in foods.

(c) Environmental impacts from its use or manufacture;

There are no environmental impacts from the production of Grape Skin Extract or its use in foods.

(d) Effects on human health

As described above, no relevant toxicological data has been found for Grape Skin Extract. However, grapes, including their skins, have been a common component of the human diet throughout history, and no adverse human health effects have been reported.

As noted above, preparations of Grape Skin Extract have very high concentrations of anthocyanin compounds. These naturally occurring antioxidants have been shown to be effective free radical scavengers in the body. The intake of natural antioxidants promotes general good health, and some evidence suggests that they reduce the risks of cancer, the neurodegenerative effects of aging, and the risks of developing cardiac diseases.

(e) Effects on soil organisms, crops, or livestock.

There is no evidence of any effect from Grape Skin Extract on soil organisms, crops, or livestock from the production of Grape Skin Extract.

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

The Material Safety Data Sheet for Grape Skin Extract is available and included as Attachment #4. No substance report for Grape Skin Extract from the National Institute of Environmental Health Studies was found.

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. For petitions to include non-organic agricultural substances onto the National List, this information item should be responded to with research concerning the availability of organic alternatives.

Safety Reviews:

JECFA (1982). Toxicological evaluation of certain food additives. WHO Food Additives Series No. 17. Twenty-sixth meeting of the Joint WHO/FAO Expert Committee on Food Additives.

References:

Becci P.J., Hess F.G., Gallo M.A., Johnson W.D. and Babish J.G. (1983a) Subchronic feeding study of grape colour extract in beagle dogs. *Food Chemical Toxicology* **21**, 75-77.

Becci P.J., Hess F.G., Babish J.G., Gallo M.A. and Voss K.A. (1983b) Reproduction study of grape colour extract in rats. *Food Chemical Toxicology* **21**, 79-83.

Brown J.P. & Dietrich P.S. (1979) Mutagenicity of plant flavonols in the *salmonella*/mammalian microsome test. *Mutation Research* **66**, 223-240.

Cox G.E. and Babish J.G. (1978) Evaluation of the safety of dietary administration of special grape color powder (Type BW-AT) on reproduction, lactation, and maturation when fed to Sprague-Dawley rats. Food and Drug Research Laboratories. Lab. No. 5417.

Ferguson L.R., van Zijl P., Holloway W.D. and Jones W.T. (1985) Condensed tannins induce micronuclei in cultured V79 Chinese hamster cells. *Mutation Research* **158**, 89-95.

Haveland-Smith R.B. (1981) Evaluation of the genotoxicity of some natural food colours using bacterial assays. *Mutation Research* **91**, 285-290.

Horwitt M.K. (1933) Observations on behavior of the anthocyan pigment from concord grapes in the animal body. *Proceeding of the Society for Experimental Biology and Medicine* **30**, 949-951.

MacGregor J.T. & Jurd L. (1978) Mutagenicity of plant flavonoids: Structural requirements for mutagenic activity in *Salmonella typhimurium*.. *Mutation Research* **54**, 297-309.

Marmion, D.M.; Handbook of U.S. Colorants for Foods, Drugs, Cosmetics and Medical Devices. 3rd Ed.; John Wiley & Sons, Inc.: New York, New York, 1991.

Pourrat H., Bastide P., Dorier P., Pourrat M.A. and Tronche P. (1967) Pr_paration et activit_ th_rapeutique de quelques glycosides d'anthocyanes. *Chimie Th_rapeutique* **2**, 33-38.

Stevens K.R. and Gallo M.A. (1977) Thirty-day dose range finding study of Welch's grape extract in rats. Food and Drug Research Laboratories. Lab No. 5388.

Viola M. & Nosotti A. (1978) Applicazion del test di Ames su Alcuni coloranti. *Bollettino Chimico Farmaceutico* **117**, 402-415.

Commercial Availability Research:

As justification for this petition to place Grape Skin Extract for use as a food coloring substance on National List section §205.606, we have done considerable research into the commercial availability of organic forms of Grape Skin

CBI Deleted—commercial availability information

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12. Petition Justification Statement which provides justification for any of the following actions requested in the petition:

Natural colors have historically been an essential component of many food products. Practically all consumers judge the palatability of foods not only on flavor, texture, and aroma, but also on appearance. A large number of these consumers would find foods that did not meet their expectations for vibrant yet reliable colors to be unappealing and perhaps would suspect that they are not sufficiently nutritious or even, in some cases, safe to eat. Consumer acceptance of these foods is therefore based in large part upon the ability of processed food manufacturers to utilize food colors to maintain expected and desirable appearances for their products.

Organic consumers expect no less from their foods. Organic foods are chosen by consumers because they know that they are healthy and reliable, but also because they look good to consumers. For many foods, a large part of this positive appearance is due to the use of natural colors. Packaged organic black cherry yogurt looks like delicious yogurt with fresh black cherries swirled in because of the addition of grape juice. Organic portabello mushroom veggie hot dogs resemble a “traditional” hot dog due to the addition of paprika. Organic strawberry cheesecake looks like, well, strawberry cheesecake through the addition of beet juice. In all cases, the consumer is guaranteed that in addition to the great flavor and health benefits of eating organic foods, they also have the expected appearance and a highly desirable palatability.

The use of natural colors in organic and traditional foods is critical due to the processes involved in food production. In many processes there is at least one and occasionally several heating steps involved in the conversion of raw ingredients to final food products. In other cases the blending of ingredients changes the pH or increases the rate of oxidation. These have a deleterious effect on the colors in the raw materials, turning a bright red strawberry into something else entirely—something that consumers of traditional and organic foods might find unpalatable. Supplementing or replacing the naturally-contained color in the raw materials of food products with small amounts of natural colors ensures that the finished food products maintain the appeal of natural, unprocessed foods.

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Conclusions:

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While IACM supported the renewal of "Colors, non-synthetic sources only" to the National List section 205.605(a), we do recognize that there were procedural difficulties with its initial placement on the National List that warranted its removal for legal reasons. The members of IACM have substantial interest in the potential growth of the organic industry, and we see the value in developing certified organic processes for our coloring materials. Should this petition be approved, Grape Skin Extract used as a coloring material will be supplied to our organic customers by our member companies **only** until such a time as processes for certified organic Grape Skin Extract that can be used as a coloring material are commercially available. Until that time, our customer organic handlers will be able to incorporate a spectrum of vibrant natural colors into their products, and the consumers will continue to purchase organic food products that meet their desires for a healthy, colorful diet.

13. Commercial Confidential Information Statement:

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List of Attachments:

Attachment #1: Technical Advisory Panel Review of "Colors, Non-Synthetic Sources Only"
Attachment #2: JECFA Evaluation of Anthocyanins
Attachment #3: Label(s) of Products containing Grape Juice
Attachment #4: Material Safety Data Sheet for Grape Juice used as a coloring material

OVERVIEW OF FOOD COLOR ADDITIVES

Prepared for the USDA National Organic Program and the National Organic Standards Board

October 14, 2005

This paper provides a general overview of color additives and how they are regulated in the United States. Use of colors in organic food production and potential adverse effects from the consumption of some specific colorants also are discussed.

I. EXECUTIVE SUMMARY

Colors are defined as any dye, pigment, or other substance that can impart color to a food, drug, or cosmetic or to the human body. Colors are regulated in the United States by the U.S. Food and Drug Administration (FDA) and are categorized either as "certifiable" (those derived primarily from petroleum and known as coal-tar dyes) or "exempt from certification" (those obtained largely from mineral, plant, or animal sources). Currently, there are no GRAS ("generally recognized as safe") exemptions for color additives. Consequently, all color additives are subject to premarket approval requirements. To obtain approval from FDA for a new color additive, the manufacturer must submit a petition demonstrating the safety and suitability of the new color additive or new use. FDA is then responsible for evaluating the petition and determining whether the color additive is safe for human consumption. Additionally, the decision regarding batch certification is made during FDA's review of the petition. If required, a sample from each manufactured batch must be submitted to FDA for analysis and certification. With this regulatory process, color additives generally have a good safety record; however, some adverse reactions have been noted. Specifically, allergic effects to Yellow No. 5 and carmine and cochineal extract have been observed. Additionally, possible carcinogenic effects have led FDA to ban uses of FD&C Red No. 3 and FD&C Red No. 2.

II. CHARACTERIZATION

Color additives are defined as any dye, pigment, or other substance that can impart color to a food, drug, or cosmetic or to the human body. Color additives include those that are white, black, and gray (Barrows et al., 2003). They also may include any chemical that reacts with another substance and causes formation of a color. In the United States, FDA is responsible for regulating color additives. For regulation purposes, FDA categorizes colors as "certifiable" (those derived primarily from petroleum and known as coal-tar dyes) and "exempt from certification" (those obtained largely from mineral, plant, or animal sources).

Certifiable colors can be further categorized into straight colors, mixtures, and dyes and lakes. Straight colors are those color additives that have not been mixed or chemically reacted with any other substance. Mixtures are the resulting color additives that are formed by mixing one color additive with one or more color additives or non-colored diluents, without a chemical reaction. Dyes are defined as those that "...dissolve in water

and are manufactured as powders, granules, liquids or other special purpose forms. They can be used in beverages, dry mixes, baked goods, confections, dairy products, pet foods and a variety of other products" (FDA, 1993). Lakes are the water insoluble form of the dye. Lakes tend to be more stable than dyes and ideal for coloring products containing fats and oils or items lacking sufficient moisture to dissolve dyes. Some examples where lakes are used include coated tablets, cake and donut mixes, hard candies, and chewing gums. Additionally, certifiable colors that are added to food are chemically classified as azo, xanthene, triphenylmethane, and indigoid dyes.

III. REGULATION

A. History

Color additives were initially regulated in the United States under the U.S. Department of Agriculture's (USDA) Bureau of Chemistry. In 1906, the Food and Drugs Act was passed by Congress, which prohibited the use of poisonous or deleterious colors in confectionery and the coloring or staining of food to conceal damage or inferiority. In 1927, responsibility of the Food and Drugs Act was transferred to FDA. Increasing government oversight, the Federal Food, Drug, and Cosmetic Act (FFDCA) was passed in 1938 and established the three following categories for colors:

- **FD&C:** colors used in foods, drugs and cosmetics;
- **D&C:** colors used in drugs and cosmetics when in contact with mucous membranes or ingested; and
- **Ext. D&C:** colors used in products applied externally.

The FFDCA mandated a listing of those coal-tar colors that were determined to be "harmless and suitable" for use in foods, drugs, and cosmetics. FDA interpreted "harmless" to mean harmless at any level (Francis, 2000). Additionally, the FFDCA required the listing of new colors, mandated the previously voluntary certification program for batches of listed color with associated fees, and contained adulteration and misbranding provision for the use of coal-tar colors in food, drugs, and cosmetics (Barrows et al., 2003).

The Color Additive Amendments to the FFDCA were established in 1960 because FDA's interpretation of "harmless" was not workable. Under the Color Additive Amendments, "color additives" were defined and a requirement was established that only color additives (except coal-tar hair dyes) listed as "suitable and safe" for a given use could be used in foods, drugs, cosmetics, and medical devices. A current listing of FDA approved colorants, including those that do and do not require certification, is provided in Table 1 (Barrows et al., 2003). As illustrated in Table 1, all of these colorants are straight colors.

1 **Table 1. FDA Approved Food Color Additives**

2

21 CFR Section	Straight Color	Use and Restrictions
Color Additives Subject To Certification		
74.101	FD&C Blue No. 1	Foods generally
74.102	FD&C Blue No. 2	Foods generally
74.203	FD&C Green No. 3	Foods generally
74.250	Orange B	Casings or surfaces of frankfurters and sausages, NTE 150 ppm
74.302	Citrus Red No. 2	Skins of oranges not intended or used for processing, NTE 2.0 ppm (by weight)
74.303	FD&C Red No. 3	Foods generally
74.340	FD&C Red No. 40	Foods generally
74.705	FD&C Yellow No. 5	Foods generally
74.706	FD&C Yellow No. 6	Foods generally
Color Additives Exempt From Certification		
73.30	Annatto extract	Foods generally
73.35	Astaxanthin	Salmonid fish feed
73.40	Dehydrated beets (beet powder)	Foods generally
73.50	Ultramarine blue	Salt for animal feed
73.75	Canthaxanthin	Foods generally, NTE 30 mg/lb of solid or semisolid food or per pint of liquid food; broiler chicken feed; salmonid fish feed
73.85	Caramel	Foods generally
73.90	ß-Apo-8'-carotenal	Foods generally, NTE 15 mg/lb solid, 15 mg/pt liquid
73.95	ß-Carotene	Foods generally
73.100	Conchineal extract; carmine	Foods generally
73.125	Sodium copper chlorophyllin	Citrus-based dry beverage mixes, NET 0.2% dry mix
73.140	Toasted partially defatted cook cottonseed flour	Foods generally
73.160	Ferrous gluconate	Ripe olives
73.165	Ferrous lactate	Ripe olives
73.169	Grape color extract	Nonbeverage food
73.170	Grape skin extract (enocianina)	Still and carbonated drinks and ades; beverage bases; alcoholic beverages
73.185	Haematococcus algae meal	Salmonid fish feed
73.200	Synthetic iron oxide	Sausage casings, NTE 0.1%

21 CFR Section	Straight Color	Use and Restrictions
		(by weight); dog and cat food, NTE 0.25% (by weight)
73.250	Fruit juice	Foods generally
73.260	Vegetable juice	Foods generally
73.275	Dried algae meal	Chicken feed
73.295	Tagetes (Aztec marigold mean and extract)	Chicken feed
73.300	Carrot oil	Foods generally
73.315	Corn endosperm oil	Chicken feed
73.340	Paprika	Foods generally
73.345	Paprika oleoresin	Foods generally
73.355	Phaffia yeast	Salmonid fish feed
73.450	Riboflavin	Foods generally
73.500	Saffron	Foods generally
73.575	Titanium dioxide	Foods generally, NTE 1% (by weight)
73.600	Turmeric	Foods generally
73.615	Turmeric oleoresin	Foods generally

The Color Additive Amendments also established the "Delaney Clause" that prohibited the listing of a color additive shown to be carcinogenic.

B. Petition Process

Under the current regulatory system, FDA is responsible for ensuring the safety of new food additives, including colors. However, food additive petitions are not required for food additives that are identified as "generally recognized as safe" (GRAS) substances. Currently, there are no GRAS ("generally recognized as safe") exemptions for color additives. Consequently, all color additives are subject to premarket approval requirements. These requirements are listed in Title 21 of the Code of Federal Regulations (CFR), Part 71. In filing a color additive petition, the manufacturer is responsible for providing FDA with information including, but not limited to the following:

- Identification of the food additive;
- Physical, chemical, and biological properties;
- Chemical specifications;
- Manufacturing process description;
- Stability data;
- Intended uses and restrictions;
- Labeling[1];

[1] Any labeling that will be required by applicable provisions of the FFDCA on the finished food by reason of the use of the food additive.

- Tolerances and limitations[2];
- Analytical methods for enforcing chemical specifications;
- Safety studies; and
- Estimate of probable exposure.

C. Safety Assessment

A color additive petition must demonstrate the safety and suitability of the new color additive or new use. FDA is responsible for evaluating petitions and determining whether the additive is safe for human consumption. Generally, this determination is made by examining the following parameters:

- History of use or natural occurrence;
- Consumption ratio, if applicable;
- Exposure levels;
- Inherent toxicity of the substance;
- Toxicological data on the substance or on structurally-related compounds; and
- Metabolism of the substance (either know of forecasted on the basis of data for structurally-related compounds).

FDA's safety assessment includes a review toxicity data such as the results of controlled animal studies. Ideally, a complete range of data, including short- and long-term toxicity studies, as well as studies that examine possible reproductive, carcinogenic, mutagenic, and sensitization characteristics of the color additive would be available for review. Sometimes a complete set of toxicology data is not available. One method of gaining additional insight on a color lacking a complete set of data is to evaluate the toxicity of structurally related substances. By evaluating structurally related substances, scientists can try to determine how the compound is absorbed, distributed, and metabolized within the body, and how it may act on target organs in the body. Based on these data and various safety factors, FDA determines a safe exposure level for the color additive.

FDA then compares the safe exposure level to the amount likely to be consumed in food taking into consideration the composition and properties of the substance and the proposed conditions of use. Because the absolute safety of any substance can never be proven, FDA must determine if the additive is safe under the proposed conditions of use, based on the best scientific knowledge available. For more information, see http://vm.cfsan.fda.gov/~dms/opa-cg8e.html.

[2] According to 21 CFR Part 571, "If the food additive is one for which a tolerance limitation is required to assure its safety, the level of use proposed should be no higher than the amount reasonably required to accomplish the intended physical or other technical effect, even though the safety data may support a higher tolerance."

D. Batch Certification

As described in Section II, FDA requires certification of every manufactured batch of some color additives. Color additives requiring and exempt from batch certification are listed in Table 1.

Batch certification is required when the composition of the color needs to be controlled in order to protect public health. Procedures for color additive batch certification are available in 21 CFR Part 80. Under these procedures, a sample from each manufactured batch of certifiable color additive, as well as a "Request for Certification," must be submitted to FDA's Color Certification Branch. The "Request for Certification" should provide information regarding the batch weight, storage conditions, and the use for which it is being certified. FDA is then responsible for evaluating the batch's physical appearance and performing chemical analyses including, but not limited to the following:

- Purity (total color content);
- Moisture;
- Residual salts;
- Unreacted intermediates;
- Colored impurities other than the main color;
- Any other specified impurities; and
- Heavy metals (lead, arsenic, and mercury).

If the sample meets FDA's requirements, FDA will issue a certificate for the batch that identifies the color additive, batch weight, uses for which the color additive is certified, the name and address of the owner, as well as other information. The batch also is assigned a unique lot number.

Colors that are exempt from certification are usually derived from plant or mineral sources and must comply with the identity and purity specification and use limitation described in their listing regulations. According to 21 CFR 71.1(c)G, "If exemption from batch certification is requested, the reasons why it is believed such certification is not necessary (including supporting data to establish the safety of the intended use)." Consequently, a petition for exemption from certification must show why such certification is not necessary for the protection of public health (21 CFR 71.18). Color additives that are exempt from batch certification for one use may be subject to batch certification for other uses. Because natural colorants are exempt from a lengthy certification process, there has been a strong trend over the past 50 years toward the use of these color additives as compared to synthetic coal-tar dyes (Francis, 2000).

IV. ADVERSE EFFECTS

Although food colors generally have a good safety record, some adverse reactions have been noted. For example, Yellow No. 5 (listed as tartrazine on medicine labels; a color found widely in beverages, desserts, processed vegetables, drugs, makeup, and many other products) causes itching or hives in a small population sub-group (FDA, 2001).

Another color that causes allergic reactions is carmine and cochineal extract. Carmine and cochineal extract are scarlet red pigments that come from the female coccid insect *Dactylopius coccus* var. Costa (family Dactylopiidae, superfamily Coccoidea), which is parasitic on several species of cacti, particularly the cochineal figs produced by prickly pear (Opuntia) cactus *Nopalea cochenillifera*. There have been several case reports of anaphylaxis and urticaria resulting from ingestion of food or drink containing carmine (Beaudouin et al., 1995; Baldwin et al., 1997; DiCello et al., 199a,b; Chung et al., 2001).

In 1960, FDA banned uses of FD&C Red No. 3 including cosmetics and externally applied drugs because large amounts of the color caused thyroid tumors in male rats (FDA, 2001). In 1976, FDA issued a ban on FD&C Red No. 2 because there appeared to be a statistically significant increase in malignant tumors when fed high doses of the color (FDA, 2001).

V. USE OF COLORS IN ORGANIC FOODS

Colors are currently on the National List of Allowed and Prohibited Substances for use in organic foods. Colors were not added to the National List as the result of a petition. Instead, they were included among substances initially placed on the National List when USDA promulgated regulations pursuant to the Organic Food Production Act of 1990. According to 21 CFR Part 205.605, nonagricultural (nonorganic) colors are allowed as ingredients in or on processed food products labeled as "organic" or "made with organic." Only nonsynthetic colors (as a group) are allowed.

References:

Baldwin J.L., Chou A.H., and Solomon W.R. 1997. Popsicle-induced anaphylaxis due to carmine dye allergy. Annals of Allergy, Asthma & Immunology 79:415-419.

Barrows J.N., Lipman A.L., Bailey C.J. 2003. Color Additives: FDA's Regulatory Process and Historical Perspectives. Available at: http://www.cfsan.fda.gov/~dms/col-regu.html.

Beaudouin E., Kanny G., Lambert H., Fremont S., Moneret-Vautrin D.-A. 1995. Food anaphylaxis following ingestion of carmine. Annals of Allergy, Asthma, & Immunology 74: 427-430.

Chung K., Baker J.R., Baldwin J.L., and Chou A. 2001. Identification of carmine allergens among three carmine allergy patients. Allergy 56(1):73-77.

DiCello M.C., Baldwin J.L., Myc A., and Baker J.R. 1999a. Anaphylaxis after ingestion of yogurt colored with carmine. Annals of Allergy, Asthma, & Immunology 82:73 (Abstract).

DiCello M.C., Myc A., Baker J.R., and Baldwin J.L. 1999b. Anaphylaxis after ingestion of carmine colored foods: two case reports and a review of the literature. Allergy and Asthma Proceedings 20:377-382.

FDA. 2001. Food Additives Fact Sheet. Available at: http://www.cfsan.fda.gov/~dms/cos-221.html.

FDA. 1993. Food, Nutrition, and Cosmetics Questions & Answers. Available at: http://www.cfsan.fda.gov/~dms/qa-topad.html.

Francis F.J. (2000) Safety assessment of flavor ingredients. In: Watson D.H. (ed.). Food Chemical Safety. Volume 2. Woodhead Publishing Limited: Cambridge, England. Pp. 173-206.

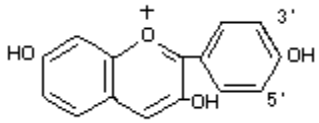
ANTHOCYANINS

Explanation

These compounds have not previously been reviewed by the Joint FAO/WHO Expert Committee on Food Additives.

Introduction

Anthocyanins represent a large group of water-soluble plant pigments of the 2-phenylbenzophyrylium (flavylium) structure (Kuhnau, 1976). The class, "Anthocyanins", consists of some 200 or more compounds (Parkinson & Brown, 1981) chemically combined to a sugar moiety (glucose < rhamnose < galactose < xylose < arabinose) of which the most common are:



Anthocyanin structure

Compound	Carbon ring B substitution 3'	5'
pelargonidin	-H	-H
cyanidin	-OH	-H
delphinidin	-OH	-OH
peonidin	$-OCH_3$	-H
petunidin	$-OCH_3$	-OH
malvidin	$-OCH_3$	$-OCH_3$

The blue to red colour imparted by the anthocyanins depends largely upon the pH of the medium (Francis, 1977). The anthocyanins normally exist as glycosides; the aglycone component alone is extremely unstable.

The anthocyanin pigments present in grape-skin extract consist of diglucosides, monoglucosides, acylated monoglucosides, and acylated diglucosides of peonidin, malvidin, cyanidin, petunidin and delphinidin. The amount of each compound varies depending upon the variety of grape and climatic conditions.

BIOLOGICAL DATA

BIOCHEMICAL ASPECTS

Absorption, distribution and excretion

Anthocyanins are poorly absorbed from the gastrointestinal tract. Anthocyanins (notably delphinidin) extracted from concord grapes were administered to rats by either gavage (100 mg) or by percutaneous injection (50 mg) and the urine tested for unchanged anthocyanins by an HCl-acid red test (Horwitt, 1933). Anthocyanin was detected in the urine of rats administered anthocyanin by the percutaneous route but not by gavage. In studies in dogs (Horwitt, 1933) administered anthocyanin (500 mg) by gastric fistula, no

urinary coloration was demonstrated. However, in the rabbit, 1-2% of an oral dose of anthocyanin (500 mg) was present in the urine as the unchanged pigment. It should be noted that the HCl-acid red test used in this study would only detect unchanged anthocyanins (Scheline, 1978). If the anthocyanins were transformed into colourless pseudobases or pale anhydrolases prior to absorption and excretion, they would not be detected (Kuhnau, 1976).

The absence of pigmented urine in normal individuals ingesting anthocyanin-containing foods in humans coupled with the apparent lack of metabolism of anthocyanins has been interpreted as showing that gastrointestinal absorption of these compounds does not occur (Clark & Mackay, 1950). Clinical studies have reported anthocyaninuria in patients with a beet allergy, following the ingestion of large amounts of beets (Zindler & Colovos, 1950). However, this has been identified as betaninuria, and is related to the excretion of betanin, rather than anthocyanins (Forrai et al, 1968).

Tissue disposition of anthocyanosides derived from Vaccinium myrtillus (approximately 25% anthocyanins) was examined in Charles River rats following intraperitoneal (i.p.) or intravenous (i.v.) injection. Following acute administration by either route, anthocyanins were found to distribute rapidly into the tissues.

Accumulation was primarily in the kidney, skin, liver, heart and lung (Lietti & Forni, 1976). There was also some indication of lymph node uptake of the anthocyanins. Elimination of the compound occurred primarily via the kidney (25-29%/24 hours) and bile (15-18%/24 hours). Because of the high urinary excretion rate in these studies, the anthocyanins are considered to be eliminated by both glomerular filtration and renal tubular excretion (Lietti & Forni, 1976).

Metabolism

Studies in rats have shown that some anthocyanins (notably pelargonidin, delphinidin, malvidin) were subject to degradation by intestinal bacteria (Griffiths & Smith, 1972a, b). p-hydroxyphenyl-lactic acid was detected in the urine of rats following the oral administration of pelargonidin (a 3',3-diglycoside of pelargonidin). Decoloration of "anthocyanin" by rat caecal cell extracts has been reported (Haveland-Smith, 1981). Anthocyanin extracts incubated with human faecal suspensions for 2-3 days remained unchanged (as measured by a reduction in suspension colour).

The presence of 2 unidentified metabolites in the urine of rats after gavage with 100 mg of delphinidin has also been reported (Scheline, 1978). Rats gavaged with malvidin (a 3',5'-diglycoside of malvidin) had 3 unidentified metabolites present in the urine. These studies suggest that some of the metabolites of anthocyanins (aglycones) can be absorbed. Metabolism of anthocyanins may occur to a limited degree by ring fission and/or glycoside hydrolysis of the anthocyanins (Parkinson & Brown, 1981). Cyanidin, the most widespread anthocyanin, has not been shown to be attacked by intestinal bacteria (Scheline, 1968; Griffiths & Smith, 1972a).

Effects on enzymes and other biochemical parameters

Both pelargonidin and delphinidin have been shown to inhibit aldoreductase in the lens of rats (Varma & Kinoshita, 1976). In other studies, anthocyanin-3-monoglycosides (namely petunidin-, delphinidin- and malvidin-) extracted from grapes were found to increase the activity of alpha glucan phosphorylase and glutamic acid dicarboxylase but inhibit glycerol dehydrogenase, malate dehydrogenase and hexokinase (Carpenter et al., 1967).

Other studies have shown that anthocyanins are capable of chelating ions such as copper (Somaatmadja et al., 1964) and iodide (Moudgal et al., 1958). The iodide ion was observed in vitro to form a stable complex with the anthocyanins (Moudgal et al., 1958).

TOXICOLOGICAL STUDIES

Special studies on mutagenicity

Cyanidin chloride was not mutagenic when examined in the Ames assay using Salmonella typhimurium strain TA-98 with and without metabolic activation (arochlor 1254 induced rat liver S-9 fraction) (MacGregor & Jurd, 1978). Structure-activity testing of a large group of flavonols for mutagenic response in this assay system indicated that compounds of flavylium class were inactive.

Cyanidin and delphinidin were inactive in the Ames assay system using 5 different strains of Salmonella typhimurium (TA-1535, TA-100, TA-1537, TA-1538 and TA-98) with and without activation (Brown & Dietrich, 1979).

Anthocyanin was tested in both the Ames test using Salmonella typhimurium TA-1538 for mutagenicity and in another in vitro test employing E. coli Wf2 for induction of DNA damage. In both assay procedures with or without metabolic activation (using either rat caecal extracts or rat liver microsomes) anthocyanins were not found to induce any response (Haveland-Smith, 1981). Negative findings were also reported for the anthocyanins in a gene conversion assay using S. cerevisiae D4 (Haveland-Smith, 1981).

Special studies on pharmacology

In rabbits administered anthocyanin glycosides 6 g/kg (oral) or 500 mg/kg (i.p.) acutely, no adverse effect was noted on blood pressure. However, 100-200 mg/kg i.v. was shown to elicit a transcent hypotension accompanied by a decrease in respiratory amplitude. At 25 mg/kg i.v., diuretic effects were also reported. Anthocyanin also caused a vasodilation in the isolated rabbit heart (Pourrat et al., 1967).

In mice, anthocyanins given in oral doses of 500 mg/kg produced a sedative effect on the animals (Pourrat et al., 1967).

Improvements in visual acuity and darkness adaptation have been reported in humans for a short period of time, after receiving oral doses of up to 700 mg of the anthocyanins (Pourrat et al., 1967).

Special studies on reproduction

A 2-generation reproduction study was performed in rats (Sprague-Dawley) ingesting a grape-skin extract preparation that was prepared by spray drying the liquid form of the extract after addition of a carrier material (malto-dextrose). The preparation

contained approximately 3% anthocyanins. The test group received dietary levels of 7.5% or 15% of the grape-skin extract throughout the study. There were two concurrent control groups, one receiving the basal diet, the other receiving a diet containing 9% of the malto-dextrin used as a carrier to the grape-skin extract preparation. The F_{2a} generation (10/litter culled at 4 days) were maintained for 21 days post-partum, then autopsied. No differences in reproduction performance or indices including pup viability were apparent between control and dosed groups. At the high-dose level, both the F_{1a} and F_{2a} rats exhibited lower body weights than the concurrent controls. Body weights of the F_2 pups in the 7.5% group were marginally depressed. However, it should be noted that the

decrease in body weights was accompanied by a concomitant decrease in food intake. At week 6 and at termination of the studies, haematological and blood serum chemistry and urinalyses were carried out in the F_{1a} group. There were no compound-related effects. At week 18 of the study, rats in the F_{1a} group were sacrificed and absolute and relative organ weights determined, and a complete histological study was carried out in the principal organs and tissues. Decrease in organ weights of the liver, adrenal and thyroid occurred in the 15% group. There were no compound-related histological effects (Cox & Babish, 1978a).

Special studies on teratogenicity

The anthocyanin glycosides (an extract from currants, blueberries and elderberries) were reported not to be teratogenic in rats, mice or rabbits when given at dose levels of 1.5, 3 or 9 g/kg over 3 successive generations (Pourrat et al., 1967).

Acute toxicity

Animal	Route	LD_{50} (mg/kg bw)	Reference
Mice	i.p.	4 110	Pourrat et al., 1967
	i.v.	840	Pourrat et al., 1967
	Oral	25 000	Pourrat et al., 1967
Rats	i.p.	2 850	Pourrat et al., 1967
	i.v.	240	Pourrat et al., 1967
	Oral	20 000	Pourrat et al., 1967

Test animals were administered the anthocyanins (cyanidin, petunidin and delphinidin mixture extracted from currants, blueberries and elderberries) in doses from 0 to 25 000 mg/kg bw for mice and from 0 to 20 000 mg/kg for rats. Following i.v. or i.p. administration, toxic doses of anthocyanins produced sedation, convulsions and finally death.

Short-term studies

Weanling male and female Wistar rats (20/group) were fed a diet containing anthocyanin extract at levels equivalent to 3000 mg/day or 6000 mg/day for a period of 90 days. A group of concurrent controls were also used in the study. The doses of anthocyanin administered were estimated to be 5 and 10 times, respectively, the level that a human would ingest. No differences were observed between the test animals and controls in survival, growth or histopathology of the principal tissues at the termination of the study (Pourrat et al., 1967).

In another study, guinea-pigs received 3000 mg/kg of anthocyanin in the diet for 15 days. No adverse effects were reported (Pourrat et al., 1967).

Male and female beagle dogs (4/sex/dose) received either 0, 7.5% or 15% of grape-skin extract (approximately 2.39% anthocyanin by weight) in the diet for 90 days. No differences were noted between control and treated animals in body weights, growth, survival, clinical chemistries (haematology, biochemistry or urinalysis), organ weights or pathological lesions (gross or microscopic) (Cox & Babish, 1978a).

OBSERVATIONS IN MAN

Man is naturally exposed to anthocyanins through the ingestion

of fruits and vegetables. Levels of exposure under normal dietary conditions have not been established.

Information on the metabolism and toxicity of the anthocyanins is limited. Its interpretation is complicated because the anthocyanins represent a large group of chemically-related substances and the effect observed with one defined anthocyanin may not be applicable to another. The available information suggests that anthocyanins are poorly absorbed from the gastrointestinal tract. Metabolism is limited and may be due to the activity of the intestinal bacterial flora. The metabolites of anthocyanins have not been identified. However, the insensitivity of the assay techniques used for measuring unmetabolized anthocyanins may result in a significant underestimate of the degree of absorption and metabolism of the anthocyanins (Kuhnau, 1976).

Comments

Toxicological studies are limited, and have been carried out with mixtures extracted from a variety of fruits. The available data indicate that such extracts are of a very low order of toxicity. Diets containing 7.5% or 15% of a grape-skin extract preparation (approximately 3% anthocyanin) had no effect on the reproductive performance of rats in a 2-generation reproductive study. The lower body weights of offspring were related to a concomitant decrease in food intake. At the highest level tested, there was a decreased organ weight of the liver, adrenal and thyroid. There were no compound-related histological effects. No compound-related effects were observed in a short-term study in which dogs were fed diets containing 7.5% or 15% of the grape-skin extract preparation.

EVALUATION

Level causing no toxicological effect (Grape-skin extract preparation)

Rat (young): 7.5% of the diet equivalent to 7500 mg/kg bw.

Estimate of acceptable daily intake for man

0-2.5 mg/kg bw.*

---

* Anthocyanins (present in the grape-skin preparation at level of approximately 3%).

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See Also:
Toxicological Abbreviations
ANTHOCYANINS (JECFA Evaluation)

64oz. Grape Juice

Contains:
filtered water, grape juice concentrates (white, red and concord juice concentrates), grape skin extract (color), natural flavor, tartaric acid, vitamin c.

Nutritional Facts:
Serving Size 8 fl. oz. (240mL) Servings Per Container:8, Amount Per Serving: Calories 160; Calories from Fat 0, Total Fat 0g 0%, Saturated Fat 0g 0%, Cholesterol 0mg 0%, Sodium 15mg 1%, Potassium; 270mg 8%, Total Carb 40g 13%, Dietary Fiber 0g 0%, Sugars 39g, Protein 0g, Vitamin A 0%, Vitamin C 120%, Calcium 2%, Iron 4%

Nutrition Facts

Serving Size 8 fl oz (240 mL)
Servings Per Container 2.5

Amount Per Serving	8 fl oz	%DV*	Per Bottle	%DV*
Calories	50		120	
Total Fat	0g	0%	0g	0%
Sodium	25mg	1%	65mg	3%
Total Carb.	13g	4%	32g	11%
Sugars	13g		31g	
Protein	0g		0g	
Vitamin C		100%		250%
Vitamin E		20%		50%
Niacin		10%		25%
Vitamin B6		10%		25%
Vitamin B12		10%		25%
Pantothenic Acid		10%		25%

Not a significant source of calories from fat, saturated fat, trans fat, cholesterol, dietary fiber, vitamin A, calcium and iron.

*Percent Daily Values are based on a 2,000 calorie diet

CONTAINS: FILTERED WATER, CRYSTALLINE FRUCTOSE, NATURAL FLAVOR, CITRIC ACID, ASCORBIC ACID (VITAMIN C), GRAPE JUICE CONCENTRATE (COLOR), GRAPE SKIN EXTRACT (COLOR), SODIUM CITRATE, DL-ALPHA-TOCOPHERYL ACETATE (VITAMIN E), NIACIN, CALCIUM PANTOTHENATE, PYRIDOXINE HYDROCHLORIDE (VITAMIN B6), CYANOCOBALAMIN (VITAMIN B12).

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SAN JOAQUIN VALLEY
CONCENTRATES

Material Safety Data Sheet

Manuafacturer's Name/Address	Emergency Telephone No.
San Joaquin Valley Concentrates 5631 E. Olive Ave Fresno, CA 93727	(559) 458-2500 Date Prepared 02-Jun-99

Section 1 - Identity

Trade Name and Synonyms	Chemical Name
Grape Skin Extract Purple	N/A
Formula	Chemical Family
N/A	N/A

Section 2 - Hazardous Ingredients

Hazardous Component(s)	Percentage
Additive: Sulfur Dioxide (CAR #7446-00-5)	0 to 500 ppm

Section 3 - Physical Characteristics (Fire & Explosion Data)

Boiling Point	Specific Gravity (H2O = 1)	Vapor Pressure (mm Hg)	Solubility in Water
N/A	Ca 1.26	N/A	Complete
Percent Volatile by Volume	**Vapor Density (Air = 1)**	**Evaporation Rate**	
N/A	N/A	N/A	

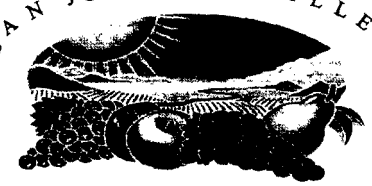
Appearance and Odor
Characteristic of Grape Ion Pigment

Flash Point	Flammable Units		Extinguisher Media
	Upper	Lower	N/A
N/A	N/A	N/A	

Special Fire Fighting Procedure
N/A

Unusual Fire and Explosive Hazards
N/A

SAN JOAQUIN VALLEY



CONCENTRATES

Section 4 - Physical Hazards

Stability Unstable [ ] Stable [X]	Conditions to Avoid N/A
Incompatibility (Materials to Avoid) N/A	
Hazardous Decomposition Products N/A	
Hazardous Polymerization May Occur [ ] Will Not Occur [X]	Conditions to Avoid N/A

Section 5 - Health Hazards

Threshold Limit Value (TLV) Not Established
Effects of Overexposure May cause mild irritation to eyes, skin and throat.
Emergency and First Aid Procedures Rinse concentrate off with water.

Section 6 - Special Protection Information

Respiratory Protection N/A			
Ventilation			
Local Exhaust N/A	Mechanical (General) N/A	Special N/A	Other N/A
Protective Gloves Impervious plastic	Eye Protection Safety Glasses	Other Protective Clothing or Equipment None	

Section 7 - Special Precautions and Spill/Leak Procedures

Precautions to be Taken in Handling and Storage Keep refrigerated. Do not keep in tightly sealed container when not being used; possibility of re-fermentation which will produce pressure.
Other Precautions None
Steps to be Taken in Case Material is Released or Spilled Wipe up or rinse into drain.
Waste Disposal Methods Small (spillage) quantity - domestic sewer or dump. Large quantity - dispose of in accordance with Federal, State and Local regulations.

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