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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5. The source of the substance and a detailed description of its manufacturing or processing procedures: Red cabbages grows as a bulbs of tightly packed leaves indigenous to Asia. The cabbages are collected, washed, and cut into small pieces. The 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 cabbage.

6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance: No such government reviews of red cabbage extract are known; but anthocyanins (particularly from grapes) have been used since antiquity to color human foods and are Generally Regarded As Safe (GRAS).

7. Information regarding EPA, FDA, and State Regulations: FDA permits the use of red cabbage extract as a color additive exempt from certification. 21 CFR 73.260 Vegetable Juice. Red cabbage 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 red cabbage 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 red cabbages 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.

Red cabbages have been consumed for centuries and their growth and ultimate consumption has the 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). Red cabbages, and the anthocyanins extracted from red cabbages, 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 red cabbage extract at 0.5% of the total formula. They do not actively seek out organic certified red cabbage 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 red cabbage 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 red cabbage extract, a.k.a. "red cabbage," 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. Lauro
(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 Red Cabbage Extract

1.2 Product Number: 2745

1.3 Ingredient Statement: Vegetable juice extract

1.4 Description of Product: A red 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	Red 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.

Bibliography

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EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance – RED CABBAGE 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 – RED CABBAGE 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 – RED CABBAGE 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.

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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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5. The source of the substance and a detailed description of its manufacturing or processing procedures: Purple carrots grow beneath the ground throughout Europe and Northern Asia. The carrots are collected, washed, and cut into small pieces. The 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 carrots.

6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance: No such government reviews of purple carrot extract are known; but anthocyanins (particularly from grapes) have been used since antiquity to color human foods and are Generally Regarded As Safe (GRAS).

7. Information regarding EPA, FDA, and State Regulations: FDA permits the use of purple or black carrot extract as a color additive exempt from certification. 21 CFR 73.260 Vegetable Juice. Purple carrot 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 purple carrot 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 purple carrots 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.

Purple carrots have been consumed for centuries and their growth and ultimate consumption has the 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). Purple carrots, and the anthocyanins extracted from purple carrots, 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 purple carrot extract at 0.5% of the total formula. They do not actively seek out organic certified purple carrot 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 purple carrot 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 purple carrot extract, a.k.a. "black carrot," 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. Lauro
(Name & Title)

DD WILLIAMSON, INC.
a Kentucky corporation

By: Margaret A. Lawson
Margaret A. Lawson
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VP Science & Innovation

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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 Purple Carrot Extract

1.2 Product Number: 2885

1.3 Ingredient Statement: Vegetable juice

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 – PURPLE CARROT 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 – PURPLE CARROT 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 – PURPLE CARROT 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 Purple/Black Carrot Extract to the National List Section §205.606

Item A

This is a petition to amend the National List Section §205.606 to include Purple/Black Carrot 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.

Purple/Black Carrot Extract is the common name for the scientific varieties of *Apiaceae daucus carota.*

Other names: Purple Carrot Extract
Black Carrot Extract

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.

Purple/Black Carrot Extract is a highly colored vegetable juice that has applications in food as a coloring substance. It is used to color a variety of organic and non-organic foods, including fruit and vegetable juices, sauces, soups, non-alcoholic beverages, yogurt, confectionery (candy), and salad dressings. Purple/Black Carrot Extract adds a deep blue, purple-to-black color to foods, depending upon the exact concentration used. Purple/Black Carrot 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 73.260, Purple/Black Carrot 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.

Purple/Black Carrot Extract is currently used as a color additive in a variety of organic and non-organic food products. In organic foods, Purple/Black Carrot 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, Purple/Black Carrot Extract must be added as an individual coloring substance onto the National List. Due to the minimal processing involved in its production, Purple/Black Carrot Extract meets the current definition of an agricultural substance. This petition is to place Purple/Black Carrot Extract as an allowed non-organic agricultural ingredient under §205.606 until such an organic form of Purple/Black Carrot 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.

Purple/Black Carrot 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. Purple/Black Carrot 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, Purple/Black Carrot 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.

Purple/Black Carrot Extract is the coloring material produced from either or both purple and black carrots of *Apiaceae daucus carota*. It is commonly available for use in coloring applications as either a powder or as a liquid. Purple and black carrots grow naturally in all temperate regions and are eaten raw or cooked in many parts of the world. While they are not as common as traditional orange carrots, they are making a considerable comeback to the culinary palette, and they have along history of use.

CBI Deleted—commercial availability 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 Purple/Black Carrot 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 Purple/Black Carrot Extract.

Information about Purple/Black Carrot Extract or other forms of purple or black carrot 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 Purple/Black Carrot Extract, reviews of anthocyanins, the predominant coloring components in Purple/Black Carrot Extract, 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.

Purple/Black Carrot Extract conforms in every aspect to the requirements mandated by the Federal Food, Drug, and Cosmetic Act. Purple/Black Carrot Extract used as a coloring material is fully consistent with 21 CFR 73.260:

> Sec. 73.260 Vegetable juice.
>
> (a) Identity. (1) The color additive vegetable juice is prepared either by expressing the juice from mature varieties of fresh, edible vegetables, or by the water infusion of the dried vegetable. The color additive may be concentrated or dried. The definition of vegetable 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 vegetable juice has been promulgated under section 401 of the act, it shall conform to such standard.
>
> (2) Color additive mixtures made with vegetable 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. Vegetable 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 Purple/Black Carrot Extract was found in the Environmental Protection Agency's (EPA) Substance Registry System (SRS).

Like all coloring materials, Purple/Black Carrot 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 major anthocyanin coloring component in Purple/Black Carrot Extract)
528-53-0 (for delphinidin, an anthocyanin coloring component in Purple/Black Carrot Extract)
643-84-5 (for malvidin, an anthocyanin coloring component in Purple/Black Carrot Extract)
134-01-0 (for peonidin, an anthocyanin coloring component in Purple/Black Carrot Extract)
1429-30-7 (for petunidin, an anthocyanin coloring component in Purple/Black Carrot Extract)
134-04-3 E163 (for pelargonidin, an anthocyanin coloring component in Purple/Black Carrot Extract)

European Community (EC) No.:

E163 (for anthocyanins)

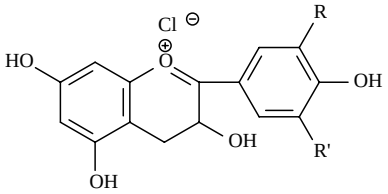
Color Index No.: None found

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.

Purple/Black Carrot Extract is an light purple-to-black powder or liquid, depending upon the processing method. Purple/Black Carrot Extract is soluble in water and mainly insoluble in ethanol and water. Although a variety of colored compounds are known to be present, the major coloring principles of Purple/Black Carrot Extract are anthocyanins.

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 black currant. 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 Purple/Black Carrot Extract is used as a coloring material.

(b) Toxicity and environmental persistence.

No relevant toxicity or environmental studies for Purple/Black Carrot Extract were found. As anthocyanins are the predominant coloring pigments found in Purple/Black Carrot 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 Purple/Black Carrot 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 Purple/Black Carrot Extract or its use in foods.

(d) Effects on human health

As described above, no studies have been conducted to gauge the genotoxicity, acute or chronic toxicity, or reproductive toxicity of Purple/Black Carrot Extract. Purple/black carrotes have a long history of being used for human consumption, often raw but also cooked and in soups. No human health concerns have been noted through the use of purple/black carrotes in any of these products.

As noted above, preparations of Purple/Black Carrot 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 Purple/Black Carrot Extract on soil organisms, crops, or livestock from the production of Purple/Black Carrot 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 Sheets for both Purple and Black Carrots and/or Extract is included as Attachment #3. No substance report for Purple/Black Carrot 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.

Information concerning the history, culinary use, and medicinal use of carrots is found in Attachment #4.

CBI Deleted

Commercial Availability Research:

As justification for this petition to place Purple/Black Carrot 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 Purple/Black Carrot Extract.

CBI Deleted—commercial availability information

CBI

CBI Deleted

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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CBI

The members of IACM have a long history of working with the US Food and Drug Administration (FDA) and with international regulatory bodies such as the Joint Expert Committee on Food Additives (JECFA) to ensure that our coloring materials are safe and conform to the expectations of governments, customer companies, and consumers. We feel strongly that our relationship with the National Organic Program (NOP) and the National Organic Standards Board (NOSB), while it has just begun, will also be positive and productive for all involved while being in the best interests of the consumer and of the organic industry in general. To that end, the members of IACM that produce natural colors currently and in the future will produce food colors that can meet the requirements of the National Organic Program.

Conclusions:

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CBI Deleted—commercial availability information

CBI

The scheduled sunset date for “Colors, non-synthetic sources only” will create a vacuum for organic handlers who incorporate natural colors into their food products. This petition, among others filed by us and others for natural colors, will work to fill this vacuum, and will provide organic handlers and the growing organic industry with a necessary continuity that is essential to eliminate the possibility of disruptions in production, the need for product reformulation, and the requirements for new product labeling. While work towards a certified organic process for Purple/Black Carrot Extract used as a coloring material continues, this petition and others will work to minimize the potential impact of the October 2007 sunset for “Colors, non-synthetic sources only” to the organic industry.

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, Purple/Black Carrot 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 Purple/Black Carrot 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:

CBI Deleted—commercial availability information

CBI

List of Attachments:
Attachment #1: Technical Advisory Panel Review of “Colors, Non-Synthetic Sources Only”
Attachment #2: JECFA Evaluation of Anthocyanins
Attachment #3: Material Safety Data Sheet for Purple/Black Carrot Extract used as a coloring material
Attachment #4: Information concerning the history, culinary use, and medicinal use of carrots
Attachment #5: Commercial Availability Information (CBI—deleted in CBI-deleted version)

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.

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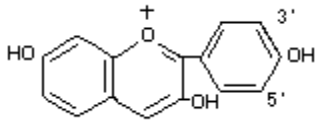
ANTHOCYANINS

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.*

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

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See Also:
Toxicological Abbreviations
ANTHOCYANINS (JECFA Evaluation)

#7614

MATERIAL SAFETY DATA SHEET

1. MANUFACTURER AND PRODUCT NAME:

1.1. TRADE NAME: **BLACK CARROT EXTRACT CONCENTRATE** **REF.: SAMPLE N° ME-06/1178**

1.2. CHEMICAL NAME AND SYNONYMS: N.A.

1.3. CHEMICAL FAMILY: N.A

1.4. MANUFACTURER: DEPROVESA WILD S.A.
Ptda. de la Coma S/N
E-46740 Carcaixent (Spain)

1.5. EMERGENCY TELEPHONE NUMBER: 34 96 246 71 50 workdays from 8.30 to 5.30 or emergency number for poisoning matters.

2. COMPOSITION / INFORMATION ON INGREDIENTS:

	CAS NUMBER	CLASSIFICATION
Black Carrot Juice and Extract, Concentrate	-------	No dangerous good

3. HAZARDS IDENTIFICATION:

3.1. MOST IMPORTANT HAZARDS

NO DANGEROUS GOOD
This product do not correspond to the criteria concerning hazardous products (EEC 93/112)

3.2. SPECIFIC HAZARDS

4. FIRST AID MEASURES

4.1. SKIN: None

4.2. EYES: Flush with cool water.

4.3. INHALATION: None

4.4. INGESTION: None

5. FIRE FIGHTING MEASURES

5.1. EXTINGUISHING MEDIA: Non flammable product. Use water

5.2. PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS: No special fire fighting protective equipment and procedures.

5.3. HEAT EXPOSURE OF DRUMS OR CONTAINERS: No explosion hazard or unusual fire

6. ACCIDENTAL SPILLAGE MEASURES

6.1. PERSONAL PRECAUTIONS: Use protective equipment to avoid contact with skin, eyes.

6.2. ENVIRONMENTAL PRECAUTIONS: Due to the tinctorial properties of this product, avoid the contamination of drains. Do not let the product to reach surface waters.

6.3. CLEANING METHODS: Use absorbent materials as sand, sawdust, earth or another adsorbents to contain the spillage.

7. HANDLING AND STORAGE

Keep the product closed in the original package under cooling conditions.

8. EXPOSURE CONTROLS/ PERSONAL PROTECTION

8.1. ENGINEERING CONTROLS: Non applicable

8.2. EXPOSURE LIMIT VALUES: Non applicable.

8.3 PERSONAL PROTECTION:

Eye Protection.
Face shields or safety glasses provide necessary eyes protection.

Hand/Skin Protection
Solvent resistant gloves, boots and clothes should be worn to prevent skin dyeing.

Respiratory Protection
None

8.4. INDUSTRIAL HYGIENE: In accordance with good manufacturing and industrial practices.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE:	Dark red purple liquid
ODOUR:	Typical from vegetable extracts
pH (5 % solution):	< 4.0
BRIX (20°C)	40 - 42° Brix.
BOILING POINT:	N.A.
FLASH POINT:	N.A. (>100° C)
AUTOIGNITION TEMPERATURE:	N.A.
VAPOUR PRESSURE:	N.A.
SPECIFIC GRAVITY:	1.1785 - 1.1888 gr/cc at 20°C
WATER SOLUBILITY:	100 %
EVAPORATION RATE:	<1 (Ether=1)

10. REACTIVITY AND STABILITY

10.1. STABILITY: Stable under normal conditions of storage and use.

10.2.CONDITIONS TO AVOID: In order to prevent the colour degradation, avoid storage under high temperature and light exposure conditions

10.3. INCOMPATIBILITIES: Powerful oxidizing agents such as perchloric acid.

10.4. HAZARDOUS DECOMPOSITION PRODUCTS: None.

11. TOXICOLOGICAL INFORMATION

11.1. TOXICITY: No data available

11.2. EFFECTS OF OVEREXPOSURE: Inhalation - No breathing difficulty.
Ingestion - No health hazard.
Exposure Limits - None known.
Signs and Symptoms of Overexposure - Unknown

12. ECOLOGICAL INFORMATION

12.1. GENERAL INFORMATION: Due to the tinctorial properties of this product, avoid the contamination of drains. Do not let the product to reach surface waters.

13. DISPOSAL CONSIDERATIONS

NO DANGEROUS GOOD. The material is biodegradable and not harmful.

14. TRANSPORT INFORMATION

ADR/ RID
Item
UN Nr.
IATA/ICAO

15. REGULATORY INFORMATION

15.1. EC CLASSIFICATION

Danger Symbol: NO DANGEROUS GOOD
Danger Description: NO DANGEROUS GOOD
Risk Phrases:

Safety Phrases:

16. OTHER INFORMATIONS

16.1. USES: As colouring agent in foodstuff.

16.2. The information in this MSDS has been obtained by bibliographic revisions and by our own knowledge.

16.3. Date of preparation: 5/May/2006
Date of issue: 10/05/06

#4039

DIANA VEGETAL, INC.
707 Executive Drive,
Valley Cottage, New York 109 9
USA

DIANA VEGETAL MSDS LETTER

Most of the products manufactured by DIANA VEGETAL, vegetable extracts and powders, as well as all fruit powders and extracts are chem cal free*.

Most of them are processed by water extraction*. Due to this process, no MS DS is required.

Most of DIANA VEGETAL products* have been evaluated and have b en determined to be non-hazardous under the Occupational Safety and He: lth Administration's Hazard Communication Standard (29 CFR 1910.120).

To the best of our knowledge, our products meet the requirements of th : Federal Drug Administration as well as U.S.D.A requirements.

* For exemptions, pleasc refer to technical data sheet. The MSDS is attached to it.

Sincerely Yours,

Antrain – 1st January, 2005

Valid up to December 31st, 200

Guy DURAND
QUALITY MANAGER

AND COOKING

THE SCIENCE AND LORE OF THE KITCHEN

HAROLD McGEE

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Root Vegetables

Beets

Beets have been eaten by man since prehistory, and are native to a wide swath of Eurasia from Britain to India. In the 18th century, a white variety of beet began to be cultivated for sugar production. Up to 8% of its weight is sugar, an exceptional figure for a vegetable. The beet consists mostly of a swollen hypocotyl, or lower stem, although it is partly a root. The ability to metabolize the bright red pigment, betacyanin, is controlled by a single genetic locus; those people who have inherited two recessive genes pass the pigment in their urine.

The Cabbage Family: Radish, Turnip

The radish is a native of the eastern Mediterranean, and was cultivated by the ancients. Like the beet, it is a swollen hypocotyl, and only partly a root. Most of the enzyme responsible for its hot taste—it reacts with another substance to form a mustard oil—is located in the skin, and peeling will therefore moderate its effects. The turnip has been under cultivation for about 4000 years in Eurasia as a staple, starchy food. It consists of both hypocotyl and taproot, and is now used mainly by the poor and for animal fodder.

The Carrot Family: Carrot, Parsnip

The carrot is native to Afghanistan, and was known to the Greeks and Romans, although it was not widely used in Europe until the Middle Ages. Early varieties were red, purple, or black with anthocyanin pigments. A pale, yellow anthocyanin-less strain arose in the 16th century and became very popular, perhaps because it would not color sauces and soups. It was in 17th-century Holland that the familiar orange type, rich in carotene (the precursor of vitamin A), was developed. The carrot was brought by the colonists to the New World, where it escaped from cultivation to become the wildflower Queen Anne's lace. It has always been less popular here than in Europe, and has been commonly used in this country only since World War I. Anatomically, the carrot is the swollen base of the taproot.

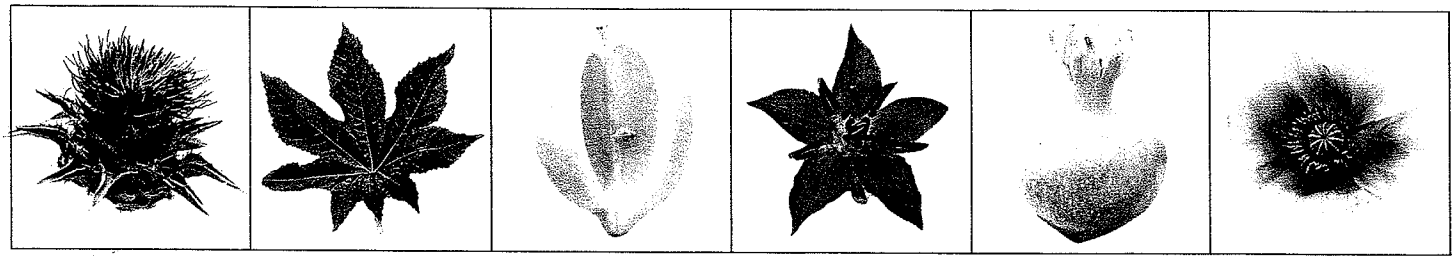
The parsnip is native to Eurasia and was known to the Greeks and Romans; the variety known to us today was developed in the Middle Ages. It too is a taproot, and like the turnip was a very important staple food before the introduction of the potato.

Tuber Vegetables

Potato

The potato, a relative of tobacco and the tomato, is indigenous to Central and South America, from the southern United States to the tip of Chile.

ANDREW CHEVALLIER



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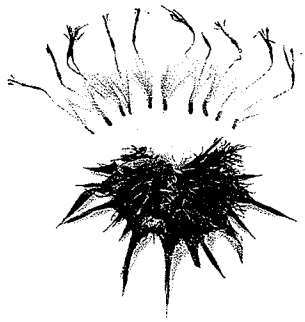

"First the word, then the plant, lastly the knife."
Aesculapius of Thassaly *c.* 1200 BC

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IMPORTANT NOTICE

Do not try self-diagnosis or attempt self-treatment for serious or long-term problems without first consulting a qualified medical herbalist or doctor. Do not take any herb without first checking the cautions in the relevant herb entry (see pp. 54–281) and the Essential Information on pp. 298–299. Do not exceed any dosages recommended. Always consult a professional if symptoms persist. If taking prescribed medicines, seek professional advice before using herbal remedies. Take care to identify plants correctly, and do not harvest restricted species.

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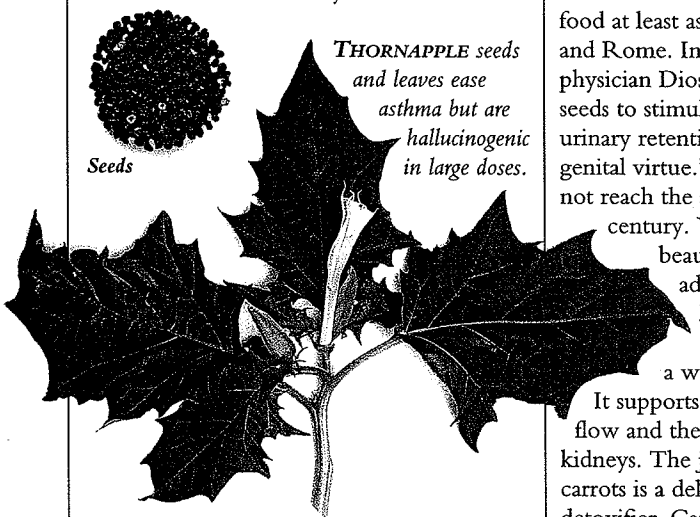
Datura stramonium
(Solanaceae)
THORNAPPLE

DESCRIPTION Robust annual growing to 3 ft (1 m). Has lobed oval leaves, long white or violet trumpet-shaped flowers, and spiny fruit capsules similar to those of the horse chestnut (*Aesculus hippocastanum*, p. 159).
HABITAT & CULTIVATION Thornapple grows in the Americas, Europe, Asia, and North Africa. It is cultivated for medicinal use in Hungary, France, and Germany. The leaves and flowering tops are harvested in summer, and the seeds in early autumn when the capsules burst.
PARTS USED Leaves, flowering tops, seeds.
CONSTITUENTS Thornapple contains 0.2–0.45% tropane alkaloids (especially hyoscyamine and hyoscine), flavonoids, withanolides, coumarins, and tannins. The tropane alkaloids are similar to those found in deadly nightshade (*Atropa belladonna*, p. 66), acting to reduce secretions and relax smooth muscle.
HISTORY & FOLKLORE Thornapple has a long history of medicinal use. If taken in sufficient doses, it causes hallucinations; the Delphic oracle in ancient Greece and the Inca in South America may have used it as an aid to making prophecies. Though it is hallucinogenic, thornapple has traditionally been used to treat insanity.



MEDICINAL ACTIONS & USES At low doses, thornapple is a common remedy for asthma, whooping cough, muscle spasm, and the symptoms of Parkinsonism. It relaxes the muscles of the gastrointestinal, bronchial, and urinary tracts, and reduces digestive and mucous secretions. Like deadly nightshade, it may be applied externally to relieve rheumatic pains and neuralgia.
RELATED SPECIES *D. metel* and *D. innoxia*, plants native to India, are similarly employed in the treatment of asthma, coughs, fevers, and skin conditions.
CAUTIONS Take only under professional supervision. Since it is toxic at more than small doses, thornapple is subject to legal restrictions in most countries.

Daucus carota
(Umbelliferae)
CARROT

DESCRIPTION Annual (cultivated varieties) or biennial (wild). Has erect stem growing to 3 ft (1 m), feathery leaves, small white flowers, and flat green seeds. Cultivated subspecies have fleshy orange taproots.
HABITAT & CULTIVATION Wild carrot is native to Europe. Cultivated subspecies are grown around the world. The root is harvested in late summer, and the seeds are gathered in late summer or early autumn.
PARTS USED Seeds, root, leaves.
CONSTITUENTS Wild carrot seeds contain flavonoids, and a volatile oil including asarone, carotol, pinene, and limonene. Cultivated carrot root contains sugars, pectin, carotene, vitamins, minerals, and asparagine. Carrot leaves contain significant amounts of porphyrins, which stimulate the pituitary gland and lead to the release of increased levels of sex hormones.
HISTORY & FOLKLORE The origins of the familiar garden carrot are a mystery – it has been cultivated as a nutritious and cleansing food at least as long ago as ancient Greece and Rome. In the 1st century AD, the physician Dioscorides recommended the seeds to stimulate menstruation, to relieve urinary retention, and to "wake up the genital virtue." The cultivated variety did not reach the shores of Britain until the 16th century. Women of the time used its beautiful, finely divided leaves to adorn their hair.
MEDICINAL ACTIONS & USES This common vegetable is also a wonderfully cleansing medicine. It supports the liver, and stimulates urine flow and the removal of waste by the kidneys. The juice of organically grown carrots is a delicious drink and a valuable detoxifier. Carrots are rich in carotene, which is converted to vitamin A by the liver. This nutrient acts to improve night blindness as well as vision in general. The raw root, grated or mashed, is a safe treatment for threadworms, especially in children. Wild carrot leaves are a good diuretic. They have been used to counter cystitis and kidney stone formation, and to diminish stones that have already formed. The seeds are also diuretic and carminative. They stimulate menstruation and have been used in folk medicine as a treatment for hangovers. Both leaves and seeds relieve flatulence and gassy colic, and are a useful remedy for settling the digestion and upsets of the stomach.
CAUTION Do not take carrot seeds, which may be abortifacient, during pregnancy.

Desmodium gangeticum
(Leguminosae)
SALPAN

DESCRIPTION Bushy perennial growing to 4 ft (1.2 m). Has woody stems, oval leaves, white or lilac flowers, and beaded seed pods.
HABITAT & CULTIVATION Native to India, southern Asia, and Africa, salpan is found as undergrowth in tropical forests.
PART USED Root.
CONSTITUENTS Salpan contains a volatile oil and an alkaloid.
MEDICINAL ACTIONS & USES Salpan root is bitter and tonic, and is used in Ayurveda to improve poor appetite and digestion, and to treat dysentery and hemorrhoids. The plant is also given for feverish and congestive conditions such as bronchitis and asthma.
RELATED SPECIES *D. adscendens*, which grows in Africa, South America, and other tropical areas, is used in West Africa and Europe to treat asthma and liver problems such as hepatitis. Preliminary research in Ghana indicates that it has a significant protective effect on the liver.

Dianthus superbus
(Caryophyllacaea)
QU MAI, FRINGED PINK

DESCRIPTION Upright perennial herb growing to 20 in (50 cm) or more. Has narrow lance-shaped leaves and large, delicate, fragrant pink or lilac flowers.
HABITAT & CULTIVATION *Qu mai* grows in China, Japan, and Europe. It is found in clumps on hillsides and in crevices. Cultivated in eastern China, it is gathered in summer and autumn when in flower.
PARTS USED Aerial parts.
CONSTITUENTS *Qu mai* contains a volatile oil including eugenol, benzyl benzoate, and methyl salicylate.
HISTORY & FOLKLORE *Qu mai* was first mentioned in the 1st-century AD Chinese herbal known as the *Divine Husbandman's Classic (Shen'nong Bencaojing)*.
MEDICINAL ACTIONS & USES In traditional Chinese medicine (*see* pp. 38–41), the bitter-tasting *qu mai* clears "damp-heat," and has been used principally to treat hot, painful conditions of the kidneys and urinary tubules, such as kidney stones, urinary tract infections, and blood in the urine. Not used

Food Ingredient Solutions, LLC.

10 Malcolm Avenue, Unit 1
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www.foodcolor.com

Friday, January 12, 2007

Program Manager
USDA/AMS/TM/NOP
Room 4008-So., Ag Stop 0268
1400 Independence Avenue., SW
Washington, D.C. 20250

Re: Petition for National List

Dear Sir/Madam:

Please find enclosed petitions for two ingredients to be added to the National List §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as organic or made with organic ingredients.

The petitions cover the following two exempt from certification colors:

Vegetable Juice Color/Red Cabbage Juice Color 21 CFR 73.260
Vegetable Juice Color/Black Carrot Juice Color 21 CFR 73.260

I have enclosed the required documents along with completed forms from various color suppliers demonstrating the current lack of commercial availability of organic raw materials.

Please contact me if I can of further assistance.

Kindest regards,

Helen Greaves
Food Ingredient Solutions, LLC
Tel: 562-956-1577
Fax: 707-840-0519
Email: hgreaves@foodcolor.com

CBI DELETED

Food Ingredient Solutions, LLC.

10 Malcolm Avenue, Unit 1
Teterboro, New Jersey 07608
T: (201) 440-4377 F: (201) 440-4211

January 11, 2007

Petition for the Use of Black Carrot Juice Color
To be added to Section 205.606 of the National List

Item A

We are petitioning to add the non-organic substance black carrot juice color to the category of "Non-organically produced agricultural products allowed as ingredients in or on processed products labeled as "'organic" or "made with organic".

Item B

1. The common name of the substance is black carrot color or vegetable juice color.
2. The manufacturer of the product is: CBI DELETED
3. This non-organically produced agricultural ingredient imparts color to a product. The product will be used in acidic food products, including beverages, fruit preparations, confectioners and dairy products such as yogurt.
4. Not intended for crop, livestock of handling activities.
5. The production flow diagram for this item is as follows(*enzyme treatment meets requirement for non-agricultural substance "enzymes must be derived from edible, non-toxic plants, nonpathogenic fungi or nonpathogenic bacteria":

CBI DELETED

6. Not available.

7. Approved for use per 21 CFR 73.260

8. Not applicable.

9. Appearance: A purple viscous liquid. Description: A vegetable extract. Toxicity and environmental impact: Limited information available. Product is a food grade, water soluble color additive derived from black carrots.

    a. No known interactions with other substances, including substances used in organic production when used correctly.
    b. No known toxicity or environmental persistence when used correctly.
    c. Environmental impacts from its use and manufacture and correct use should be negligible.
    d. No known effects on human health.
    e. No known effects on soil organisms, crops or livestock when used correctly.

10. Report from National Institute of Environmental Health not available. MSDS attached. Product has in use in food products and permitted for food use per 21 CFR 73.260.

11. All categories of vegetable juice colors are approved for use in accordance with 21 CFR and are GRAS. This product should be allowed in non-organic products in order to maintain a standard of identity for products. For example, many fruits have a tendency to brown over time. Usage of black carrot color will provide products such as yogurt and beverages with a more consistent and stable red color thus preventing the consumer from perceiving the product as spoiled. Organic raw materials for this product are not yet fully commercially available. In theory these carrots could be grown in any part of the world where yellow carrots are grown. However, the majority of these carrots are currently sourced from India and Turkey. Only one supplier of organic black carrots has been identified in Turkey. This company reportedly supplies 1000 tons annually of organic black carrot. This is currently the only known supplier. This raw material is not sufficient to produce enough material to meet current demand. In addition, reliance on one supplier is not judicious. One bad growing season could mean no black carrot for the entire year.

12. Additional information to satisfy evaluation criteria (G) Inclusion of a non-organically produced agricultural substance onto the National List:

    a. The vegetable juice color made by concentrating the juice of black carrots. All components are GMO-free. The process used does not change the chemical structure of the black carrots. The pigment component, anthocyanins, is concentrated and standardized in the juice by removing insoluble and soluble solids. The color is created in the carrots naturally. The carrots are not genetically modified. Black carrot juice color helps to identify red to purple acidic foods to consumers and, as such, is essential. In addition ORAC testing on certain black carrot colors has shown them to be high in antioxidants and beneficial to human health.

13. Confidential business information statement: Certain information pertaining to business relationships and production processes are considered confidential and should be deleted from public copies.

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance: Black Carrot Color

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		✓		
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		✓		If used in accordance with GMP
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		✓		If used in accordance with GMP
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]				This is a natural product derived solely from vegetable sources. Any listed substance present will be naturally occurring.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		✓		This is a natural product derived solely from vegetable sources and should have no adverse effects if used in accordance with GMP
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		✓		
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		✓		
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		✓		
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		✓		
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		✓		
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		✓		
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]		✓		
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		✓		

[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: Black Carrot Extract Color

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]		X		
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		x		
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		✓		
4. Is there a natural source of the substance? [§205.600 b.1]			✓	This is a natural product derived solely from vegetable sources
5. Is there an organic substitute? [§205.600 b.1]		✓		None that we are aware of
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		✓		
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]		✓		P2195 is a natural product derived solely from vegetable sources
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	✓			
9. Is there any alternative substances? [§6518 m.6]		x		Not that we are aware of
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		x		Not that we are aware of

[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 practices?

Substance: Black Carrot Extract Color

Question	Yes	No	N/A[1]	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	
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	✓			Crop used in the production of black carrot is grown commercially.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	✓			Quantity of black carrot color used in the food product will have no significant effect on the food itself
5. Is the primary use as a preservative? [§205.600 b.4]		✓		
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]	✓			
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: 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?				These are not used during the manufacture of the product.

[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.

NOSB RECOMMENDED DECISION

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: _____ Substance: _____

A. Evaluation Criteria (Documentation attached; committee recommendation attached)

	Criteria Satisfied?
1. Impact on humans and environment	Yes ☐ No ☐ (see B below)
2. Availability criteria	Yes ☐ No ☐ (see B below)
3. Compatibility & consistency	Yes ☐ No ☐ (see B below)

B. Substance fails criteria?

Criteria category: _____

Comments:

C. Proposed Annotation: _____

_____

Basis for annotation:

To meet criteria above: ____ Criteria: _____

Other regulatory criteria: ____ Citation: _____

D. Final Board Action & Vote: Motion by: _____ Second: _____

Vote:

Yes: _____

No: _____

Abstain: _____

Agricultural		Nonagricultural		Crops	
Synthetic		Not synthetic		Livestock	
Allowed[1]		Prohibited[2]		Handling	
No restriction		Deferred4		Rejected[3]	

1—substance voted to be added as "allowed" on National List

Annotation: _____

_____

2—substance to be added to "prohibited" paragraph of National List

Describe why a prohibited substance: _____

_____

3—substance was rejected by vote for amending National List

Describe why material was rejected: _____

_____

4-substance was recommended to be deferred

Describe why deferred; if any follow-up is needed. If follow-up needed, who conducts follow-up. _____

_____

E. Approved by NOSB Chair to transmit to NOP:

_____ _____

Dave Carter, NOSB Chair Date

F. NOP Action: Include in FR to amend National List: ☐

Return to NOSB ☐ Reason: _____

_____ _____

Richard H. Mathews, Program Manager Date

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: _____ Substance: _____

Committee: Crops ☐ Livestock ☐ Handling ☐

A. Evaluation Criteria (Documentation attached; committee recommendation attached)

	Criteria Satisfied?
4. Impact on humans and environment	Yes ☐ No ☐ (see B below)
5. Availability criteria	Yes ☐ No ☐ (see B below)
6. Compatibility & consistency	Yes ☐ No ☐ (see B below)

B. Substance fails criteria?

Criteria category: _____

Comments:

C. Proposed Annotation: _____

_____

Basis for annotation:

To meet criteria above: ____ Criteria: _____

Other regulatory criteria: ____ Citation: _____

D. Recommended Committee Action & Vote: Motion by: _____

Seconded: _____

Vote:

Yes: _____

No: _____

Abstain: _____

Agricultural		Nonagricultural		Crops	
Synthetic		Not synthetic		Livestock	
Allowed[1]		Prohibited[2]		Handling	
No restriction		Deferred4		Rejected[3]	

1—substance voted to be added as "allowed" on National List

Annotation: _____

_____

2—substance to be added to "prohibited" paragraph of National List

Describe why a prohibited substance: _____

_____

3—substance was rejected by vote for amending National List

Describe why material was rejected: _____

_____

4-substance was recommended to be deferred

Describe why deferred; if follow-up is needed. If follow-up needed, who will follow up _____

_____

E. Approved by Committee Chair to transmit to NOSB:

_____ _____

Committee Chair Date

Food Ingredient Solutions, LLC. 10 Malcolm Avenue, Unit 1
Teterboro, NJ 07608
T: (201) 440-4377, F: (201) 440-4211

MATERIAL SAFETY DATA SHEET

NAME: Food Ingredient Solutions, LLC.
ADDRESS: 10 Malcolm Avenue, Unit 1, Teterboro, NJ 07608
TELEPHONE: (201) 440-4377
FACSIMILE: (201) 440-4211

DATE: January 11, 2007

SECTION I - PRODUCT INFORMATION

PRODUCT NAME: Black Carrot Extract
TECHNICAL NAME: Black Carrot Juice Concentrate Color
CLASSIFICATION CODE: Not hazardous
SYNONYMS: Purple Carrot Juice Concentrate Color
CAS NUMBER: Not Applicable

SECTION II- HAZARDOUS INGREDIENT(S)

None of the ingredients in this material meet the definition of "hazardous chemical."

SECTION III - PHYSICAL DATA

BOILING POINT (°C): Not established
MELTING POINT (°C): Liquid at room temperature
APPEARANCE AND ODOR: A purple liquid with a characteristic odor.

SECTION IV - FIRE AND EXPLOSION DATA

EXTINGUISHING MEDIA: Self-extinguishing when ignition source is removed.
SPECIAL FIRE FIGHTING PROCEDURES: This material may burn, but it will not ignite readily. Move container from fire area is it is possible to do so without risk.
UNUSUAL FIRE AND EXPLOSION HAZARD: None

SECTION V - REACTIVITY DATA

STABILITY: This material is stable.
MATERIALS/CONDITIONS TO AVOID: None.
HAZARDOUS DECOMPOSITION PRODUCTS: None
HAZARDOUS POLYMERIZATION: None.

Food Ingredient Solutions, LLC. 10 Malcolm Avenue, Unit 1
Teterboro, NJ 07608
T: (201) 440-4377, F: (201) 440-4211

SECTION VI - HEALTH HAZARD DATA

INGESTION: No product-specific health hazards.
INHALATION: No product-specific health hazards.
SKIN CONTACT: No product-specific health hazards.
EYE CONTACT: No product-specific health hazards.
OTHER EFFECTS: None.

SECTION VII - EMERGENCY FIRST AID PROCEDURES

SKIN: Wash skin wish mild soap and water to remove color.
INGESTION: Seek medical attention is large quantities of substance are ingested.
INHALATION: This material is not classified as an irritant.
EYES: Flush eyes with water for 15 minutes. Seek medical attention if irritation develops.

SECTION VIII - PERSONAL PROTECTION

EYES: Wear protective goggles.
RESPIRATORY PROTECTION: No special equipment required under normal conditions of use.
OTHER PROTECTIVE EQUIPMENT: Gloves are recommended to simplify clean-up and minimize the exposure to sensitive individuals.
WORK/HYGENIC PRACTICES: Employ good personal hygiene practices; limit direct exposure as much as possible.

SECTION IX - SPILL OR LEAK PROCEDURES

Wash with ample quantities of warm, soapy water. All spills should be thoroughly cleaned until color can no longer be detected.

DISPOSAL: Properly dispose of unused or spilled material in a sanitary landfill in accordance with local, state and Federal laws, regulations and ordinances.

SECTION X - STORAGE AND HANDLING

Store in tightly sealed containers out of direct light at ambient temperatures

CBI COPY

Food Ingredient Solutions, LLC.

10 Malcolm Avenue, Unit 1
Teterboro, New Jersey 07608
T: (201) 440-4377 F: (201) 440-4211
www.foodcolor.com

Wednesday, January 10, 2007

Dear Supplier-

In accordance with our organic policy and the new Natural Organic Program requirements, we are required to show that we have made every effort to use organic ingredients when available.

Please check whether or not you have __Black Carrot Extract Color___ commercially available in a certified organic form

_____ Available _____X___ Not Available

Comments:_____
_____
_____

Company Name:

Company Address:

Phone Number:
Fax Number:
Print Name:

CBI DELETED

Signature:
Date:

Thank you,

Helen Greaves
Food Ingredient Solutions, LLC
(562) 965-1577
(707) 840-0519 FAX
hgreaves@foodcolor.com

CBI COPY

Food Ingredient Solutions, LLC.

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T: (201) 440-4377 F: (201) 440-4211
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_____ Available ____x____ Not Available

Comments:_____

_____

_____

Company Name: ____

Company Address:

Phone Number:
Fax Number:

Print Name:
Signature:
Date:

CBI Deleted

Thank you,

Helen Greaves
Food Ingredient Solutions, LLC
(562) 965-1577
(707) 840-0519 FAX
hgreaves@foodcolor.com

Food Ingredient Solutions, LLC.

10 Malcolm Avenue, Unit 1
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www.foodcolor.com

Thursday, January 11, 2007

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Please check whether or not you have __Black Carrot Extract Color___ commercially available in a certified organic form

_____ Available ___No_____ Not Available

Comments:_____Not available

_____

_____

_____

Company Name: ____Cybercolors Ltd _____

Company Address: __Unit 8 Airport East Business Park Farmers Cross Ballygarvan Co Cork Ireland _____

_____

Phone Number: __353 21 4375755
Fax Number: __353 21 4375756
Print Name: ___Noel Sexton _
Signature: ___Noel Sexton
Date: ___Jan 11th 2007 ___

Thank you,

Helen Greaves
Food Ingredient Solutions, LLC
(562) 965-1577
(707) 840-0519 FAX
hgreaves@foodcolor.com

Helen Greaves

From: Gonzalo Balarezo [gbalarezo@imbarex.com]
Sent: Wednesday, January 10, 2007 1:53 PM
To: 'Helen Greaves'
Subject: RE: looking for organic raw materials

Dear Helen

I must inform that we currently do not carry such products.

Thank you for your interest and have a nice day!

Saludos / Best regards / Meilleures salutations,

Gonzalo Balarezo
Imbarex S.A.
TEL: +51-1-251-0000
FAX: +51-1-251-3482
www.imbarex.com

Av. Produccion Nacional 229-19A
Chorrillos, Lima 09
Peru

De: Helen Greaves [mailto:hgreaves@foodcolor.com]
Enviado el: Miércoles, 10 de Enero de 2007 02:51 p.m.
Para: 'Helen Greaves'
CC: info@foodcolor.com; inquire@colormaker.com; 'Francois Cormier'; 'Robin Coté'; 'noelsexton'; jarmao@wildflavors.com; 'Millie'; 'Jenny Feng'; 'Karen Murray'; 'Gissela Gonzales'; 'Fernando Martinez'; gbalarezo@imbarex.com; Richh@rfiingredients.com
Asunto: looking for organic raw materials

Hi-
Can you please complete the attached forms and fax back to me at 707-840-0519 (or send via email) asap. We are trying to source USDA recognized organic raw materials for red cabbage and black carrot.
Please complete the attached forms and advise if you have such products available.
I really appreciate your time.
Thank you,
Helen

Helen Greaves
Food Ingredient Solutions, LLC
1428 East 33rd Street
Signal Hill, CA 90755
mobile: 562-965-1577
tel: 562-424-4340
fax: 562-424-4142

Helen Greaves

From: Millie [mfattibene@floridafood.com]
Sent: Wednesday, January 10, 2007 1:55 PM
To: Helen Greaves
Subject: RE: looking for organic raw materials

Millie Fattibene
Florida Food Products
2331 West Highway 44
Eustis, FL 32726

We do not offer either of these products.

Millie

-----Original Message-----
From: "Helen Greaves" <hgreaves@foodcolor.com>
Sent: 1/10/2007 2:52 PM
To: "Helen Greaves" <hgreaves@foodcolor.com>
Cc: "info@foodcolor.com" <info@foodcolor.com>; "inquire@colormaker.com" <inquire@colormaker.com>; "Francois Cormier" <fcormier@colarome.com>; "Robin Coté" <rcote@colarome.com>; "noelsexton" <noelsexton@cybercolors.ie>; "jarmao@wildflavors.com" <jarmao@wildflavors.com>; "Millie" <mfattibene@floridafood.com>; "Jenny Feng" <jennyf@hiche-bio.com>; "Karen Murray" <karen.murray@overseal.com>; "Gissela Gonzales" <ggonzales@globenatural.com>; "Fernando Martinez" <fmartinez@montana.com.pe>; "gbalarezo@imbarex.com" <gbalarezo@imbarex.com>; "Richh@rfiingredients.com" <Richh@rfiingredients.com>
Subject: looking for organic raw materials

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Food Ingredient Solutions, LLC.

10 Malcolm Avenue, Unit 1
Teterboro, New Jersey 07608
T: (201) 440-4377 F: (201) 440-4211
www.foodcolor.com

Thursday, January 11, 2007

Dear Supplier-

In accordance with our organic policy and the new Natural Organic Program requirements, we are required to show that we have made every effort to use organic ingredients when available.

Please check whether or not you have __Black Carrot Extract Color___ commercially available in a certified organic form

_____ Available _____X___ Not Available

Comments:_____

Company Name: Colarome Inc.

Company Address: 5132 Bombardier Street
St-Hubert (QC)
Canada J3Z 1H1

Phone Number: (450) 766-8707
Fax Number: (450) 766-8711

Print Name: François Cormier, Vice-President RD&QC

Signature:

Date: January 11, 2007

Thank you,

Helen Greaves
Food Ingredient Solutions, LLC
(562) 965-1577
(707) 840-0519 FAX
hgreaves@foodcolor.com

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_____ Available _____X____ Not Available

Comments:_____
_____
_____

Company Name: _Ecom Manufacturing Corporation_____

Company Address: _80 Telson Rd_____
_Markham, Ontario, Canada

Phone Number: _(905) 477-2441_____
Fax Number: _(905) 477-2551_____

Print Name: __Hoody_____
Signature: _____
Date: __Jan. 11, 2007_____

Thank you,

Helen Greaves
Food Ingredient Solutions, LLC
(562) 965-1577
(707) 840-0519 FAX
hgreaves@foodcolor.com

Food Ingredient Solutions, LLC.

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Phone Number: _(905) 477-2441_____
Fax Number: _(905) 477-2551_____

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Signature: _____
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Thank you,

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hgreaves@foodcolor.com