colorMaker®

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January 15,, 2007

ORIGINAL

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

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

Dear Mr. Pooler:

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

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

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

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

Betalains: (14) beet juice; and

Other: (15) turmeric.

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

DDWilliamson
Color With Confidence

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

1. The substance's common name: Beet juice, the juice expressed by *amaranthaceae beta vulgaris* (family, genus, species). This agricultural substance is also known as "beet juice extract."

2. The producer's name, address and telephone number: There are several producers of beet juice, among them are:

2.1 Seneca Foods Corporation
3736 South Main Street
Marion, NY 14505
United States
(315) 926-8100

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

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

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

4. A list of handling activities for which the substance will be used: Beet juice develops a bright red to light pink color in organic food and beverage products, depending upon its concentration. It is used as a natural color additive to enhance the visual appeal of organic products. The color, itself, results from very high concentrations of betalain molecules in the juice of the beetroot.

5. The source of the substance and a detailed description of its manufacturing or processing procedures: Beets grow underground in North America and Europe. The beets are collected, washed, and cut into small pieces. The pieces are soaked in water and then physically pressed. The resultant liquid is mechanically filtered and concentrated, producing a dark red liquid concentrate composed of the same betalain molecules produced inside the beets.

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 beet juice are known; but betalains in general (particularly from beets) have been used since antiquity to color human food. Betalains are Generally Regarded As Safe (GRAS).

7. Information regarding EPA, FDA, and State Regulations: FDA permits the use of beet juice as a color additive exempt from certification. 21 CFR 73.40. Beet juice is also permitted as a natural color additive in foods in the European Union (E162) and throughout Asia.

8. The Chemical Abstract Service (CAS) number: There exists a specific CAS Number for beet juice. It is 7659-95-2. It should be noted that no other agricultural product produces betalains.

9. The substance's physical properties and chemical mode of action: The betalains extracted from beet juice are distinct and unique molecules. They are different from anthocyanins and carotenoids (other molecules used as natural colorants). Betalains are not sensitive to light, but they are very sensitive to heat, degrading rapidly under moderate heat (140°F or higher). Betalains display no antioxidant properties and are therefore not thought to be beneficial to human health. Beyond these unique properties, betalains do not interact with substances used in organic food production and have no impact on the environment.

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

10. Safety information about the substance: Please see the attached Material Safety Data Sheet (MSDS). Beets and beet juice, and the betalains extracted from beets, are GRAS.

11. Research information about the substance: See the attached Bibliography. There are a few leading researchers on beet juice and betalains in the US including Joachim H. von Elbe (University of Wisconsin, Madison) and I.L. Goldman (University of Wisconsin, Madison).

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, beet juice inside cut beets, 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 beet juice at 0.5% of the formula. They do not actively seek out organic certified beet juice 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 beet juice 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 or no 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 beets (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 beet juice, a.k.a. "beet juice extract," 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. Lavo
(Name & Title)

DD WILLIAMSON, INC.
a Kentucky corporation

By: Margaret A. Lawson
Margaret A. Lawson
(Name & Title)
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 Beet Juice Extract

1.2 Product Number: 2720

1.3 Ingredient Statement: Beet juice

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.

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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.

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EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance – BEET JUICE

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

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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 – BEET JUICE

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 – BEET JUICE

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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Petition to the National Organic Standards Board and the National Organic Program for the Addition of Beet Juice to the National List Section §205.606

Item A

This is a petition to amend the National List Section §205.606 to include Beet Juice 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.

Beet Juice is the common name for the juice pressed from the scientific varieties of *Amaranthaceae beta vulgaris.*

Other names: Beet Juice Powder
Beet Powder
Beetroot red

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.

Beet Juice 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 processed cheese, frosting, dairy products, yogurt, and confectionery (candy). Beet Juice adds a red or pink color to foods, depending upon the exact concentration used. Beet Juice or Beet Juice Powder 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 73.40, Beet Juice or Beet Juice Powder 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.

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

Beet Juice or Beet Juice Powder 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. Beet Juice or Beet Juice Powder 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, Beet Juice or Beet Juice Powder 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.

Beet Juice is the coloring material produced from the common beet, *Amaranthaceae beta vulgaris*. It is commonly available for use in coloring applications as either a Powder or as a liquid. Beets grow naturally in all temperate regions and are eaten raw or cooked in many parts of the world.

x

CBI

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In both cases, processing involves only aqueous extraction and physical processes, and no chemical solvent is used.

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 Beet Juice or Beet Juice Powder 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 Beet Juice or Beet Juice Powder.

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

The Joint Expert Committee on Food Additives (JECFA) has conducted two reviews of the coloring material "beet red" (which refers to various preparations of coloring materials derived from red beets) and betanin. The initial review may be found at: http://www.inchem.org/documents/jecfa/jecmono/v06je10.htm and is included here as Attachment #2. The latest evaluation may be found at: http://www.inchem.org/documents/jecfa/jecmono/v22je08.htm and is included here as Attachment #3.

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.

Beet Juice conforms in every aspect to the requirements mandated by the Federal Food, Drug, and Cosmetic Act. It is produced and sold in compliance with California's Proposition 65 (CA Health and Safety Code) and Regulations therein.

Beet Juice used as a coloring material is fully consistent with 21 CFR 73.40:

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Sec. 73.40  Dehydrated beets (beet Powder).

     (a) Identity. (1) The color additive dehydrated
beets is a dark red Powder prepared by dehydrating
sound, mature, good quality, edible beets.
     (2) Color additive mixtures made with dehydrated
beets may contain as diluents only those substances
listed in this subpart as safe and suitable for use
in color additive mixtures for coloring foods.
     (b) Specifications. The color additive shall
conform to the following specifications:

 Volatile matter, not more than 4 percent.
 Acid insoluble ash, not more than 0.5 percent.
 Lead (as Pb), not more than 10 parts per million.
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> Arsenic (as As), not more than 1 part per million.
> Mercury (as Hg), not more than 1 part per million.
>
> (c) Uses and restrictions. Dehydrated beets 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.
> (d) Labeling. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of Sec. 70.25 of this chapter.
> (e) 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.

While there are listings for Beet Juice oil and Beet Juice oleoresins in the Environmental Protection Agency's (EPA) Substance Registry System (SRS), no listing was found for Beet Juice.

Like all coloring materials, Beet Juice and Beet Juice Powder 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.:
78693-88-6 (for beetroot red)
7659-95-2 (for betanin, the predominant coloring component in Beet Juice)

European Community (EC) No.:
E162 (for beetroot red)

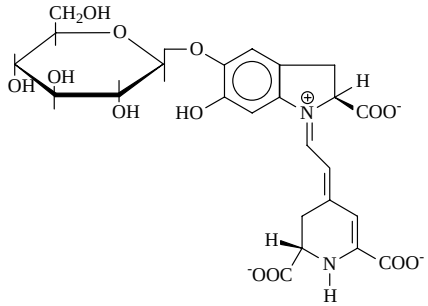
EINECS No.:
231-628-5

Color Index No.: None

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.

Beet Juice or Beet Juice Powder is obtained from the roots of the red beet *Beta vulgaris L. var rubra.* Both the juice and Powder are composed of both red pigments (betacyanins) and yellow pigments (betaxanthins), which are collectively known as betalains. Betanin, one of the betacyanins, is the main coloring principle found in Beet Juice/Beet Juice Powder. Beet Juice is miscible with water and insoluble in ethanol. It is reasonably stable in light and when it is used from pH 4 to pH 7. The degradation of beet colorant may occur at temperatures as low as 50° C, especially when exposed to air or light. It is most stable to heat in the pH range 4.0 to 5.0. Coloring materials from beets are available as a liquid, paste, or solid, depending upon the degree of processing (Marmion, 1991). Beet Juice can be converted to Beet Juice Powder by drying, and Beet Juice Powder can be dissolved in water to produce Beet Juice or Beet Juice Concentrate for use in coloring applications.



Betanin
Chemical Formula: $C_{24}H_{26}N_2O_{13}$
Molecular Weight: 550.48

(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 Beet Juice is used as a coloring material.

(b) Toxicity and environmental persistence.

Studies are summarized below for both beetroot red (Beet Juice or Beet Juice Powder) and for the major coloring pigment produced from beets, betanin.

Genotoxicity

Beetroot red is not genotoxic by weight of evidence analysis (Conforti-Froes *et al.*, 1990; Ishidate *et al*., 1984; von Elbe & Schwartz, 1981; Haveland-Smith, 1981).

Acute/Short-term Toxicity

The acute oral toxicity (LD_{50}) of beetroot red has not been reported. However 2000 ppm of the pigment, which was fed to rats for 7 days without toxic effects, is approximately 50-100 times the amount used as a food colorant (von Elbe & Schwartz, 1981). Rats given 50 mg/kg bw pure betanin in a 14-day feeding study were not adversely affected (Schwartz *et al*., 1983).

Long-term Toxicity

There were no signs of carcinogenicity in rats administered 50-77.5 mg betanin/kg bw/day via drinking water for 800 days (Druckrey, 1959).

Reproductive/Developmental Toxicity

No adverse effects were seen when two successive generations of rats were given 50-77.5 mg betanin/kg/day via drinking water for 800 days (Druckrey, 1959).

Metabolism

When infants were given beets, the pigment was rapidly excreted in the urine. The amount of pigment recovered in the urine depended on the amount of beet ingested (Adam *et al*., 1969).

Although intravenous injection of betanin in rats resulted in the immediate excretion of unchanged pigment in the urine (Watson, 1964), oral doses of it were poorly absorbed by rats, with only 3% of the dose being recovered in the urine and 3% in the feces after 24 hours (Krantz *et al*., 1980). *In vitro* studies revealed that betanin was largely metabolized in the gastrointestinal tract. Orally administered betanin is poorly absorbed because the majority of it is metabolized in the gut (Krantz *et al*., 1980).

Environmental persistence

There is no evidence of environmental persistence from the production of Beet Juice or Beet Juice Powder used as a coloring material.

(c) Environmental impacts from its use or manufacture;

There are no environmental impacts from the production of Beet Juice or its use in foods.

(d) Effects on human health

As described above, no toxicology data on Beet Juice has been found. Beets and Beet Juice have long been a part of the human diet, and this suggests that there are no adverse effects from consumption of Beet Juice.

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

There is no evidence of any effect from Beet Juice on soil organisms, crops, or livestock from the production of Beet Juice.

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

Two Material Safety Data Sheets for Beet Juice are included in Attachment #5. No substance report for Beet Juice 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 (1975). Toxicological evaluation of some food colors, enzymes, flavor enhancers, thickening agents, and certain other food additives. 18th meeting. Toxicological monographs. FAO Nutrition Meetings Report Series No. 54A; WHO Food Additives Series No. 6.

JECFA (1987). Evaluation of certain food additives and contaminants. Thirty -first report of the Joint FAO/WHO Expert Committee on Food Additives. Technical Report Series No. 759.

References:

Adam E., Farriaux J.P., and Fontaine G. (1969) Betaninuria in the infant. *Acta Paediatrica Belgium* 23, 209.

Conforti-Froes, N. et al. (1990) *Cytologia* 55, 203.

Druckrey H. (1959) Private communication. Reported in JECFA, 1975.

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

Ishidate M., Jr., Sofuni T., Yoshikawa K., Hayashi M., Nohmi T., Sawada M. and Matsuoka A. (1984) Primary mutagenicity screening of food additives currently used in Japan. *Food Chemical Toxicology* 22, 623-636.

Krantz C., Monier M. and Wahlstr_m B. (1980) Absorption excretion, metabolism and cardiovascular effects of beetroot extract in the rat. *Food Cosmetics Toxicology* 18, 363-366.

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.

National Academy of Sciences (1987) Evaluating the safety of food chemicals. Washington, D.C.

Schwartz S.J., von Elbe J.H., Pariza M.W., Goldsworthy T. and Pitot H.C. (1983) Inability of red beet betalain pigments to initiate or promote hepatocarcinogenesis. *Food Cosmetics Toxicology* 21, 531-535.

von Elbe J.H. and Schwartz S.J. (1981) Absence of mutagenic activity and a shortterm toxicity study of beet pigments as food colorants. *Archives of Toxicology* 49, 93-98.

Watson W.C. (1964) Metabolism of betanin. *Biochemistry Journal* 90, 36P.

Information on the culinary uses of Beets can found in Attachment #6.

Commercial Availability Research:

As justification for this petition to place Beet Juice 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 Beet Juice.

X

CBI

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X

CBI

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.

X

CBI

CBI Deleted

X

X

CBI

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, Beet Juice used as a coloring material will be supplied to our organic customers by our member companies only until such a time as sufficient amounts of certified organic Beet Juice that can be used as a coloring material is 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:

X

CBI

List of Attachments

Attachment #1: Technical Advisory Panel Review of “Colors, Non-Synthetic Sources Only”
Attachment #2: First JECFA Evaluation of beet red and betanin

Attachment #3: Second JECFA evaluation of beet red and betanin
Attachment #4: Label(s) of Products containing Beet Juice or Beet Juice Powder
Attachment #5: Material Safety Data Sheets for Beet Juice used as a coloring material
Attachment #6: Information concerning the culinary uses of Beets

OVERVIEW OF FOOD COLOR ADDITIVES

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

October 14, 2005

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

I. EXECUTIVE SUMMARY

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

II. CHARACTERIZATION

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

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

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

III. REGULATION

A. History

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

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

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

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

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

2

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

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

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

B. Petition Process

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

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

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

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

C. Safety Assessment

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

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

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

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

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

D. Batch Certification

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

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

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

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

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

IV. ADVERSE EFFECTS

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

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

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

V. USE OF COLORS IN ORGANIC FOODS

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

References:

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

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

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

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

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

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

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

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

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INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY

WORLD HEALTH ORGANIZATION

TOXICOLOGICAL EVALUATION OF SOME FOOD COLOURS, ENZYMES, FLAVOUR ENHANCERS, THICKENING AGENTS, AND CERTAIN FOOD ADDITIVES

WHO FOOD ADDITIVES SERIES 6

The evaluations contained in this publication were prepared by the Joint FAO/WHO Expert Committee on Food Additives which met in Rome, 4-13 June 1974[1]

World Health Organization Geneva 1975

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[1] Eighteenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 557. FAO Nutrition Meetings Report Series, 1974, No. 54.

BEET RED

BIOLOGICAL DATA

BIOCHEMICAL ASPECTS

No information available.

TOXICOLOGICAL STUDIES

Special studies on reproduction

Rat

From the 32 rats treated with betanin to a level of 17 g/animal was produced an F_2 generation of 24 pups. These received a total of 25 g betanin per animal and showed a mean life span of 800 days. Only 2 mammary fibro adenomata and no other adverse effects were seen in the test group (Druckrey, 1959).

Acute toxicity

No death could be obtained on oral administration of high doses (Druckrey, 1959).

Short-term studies

None available.

Long-term studies

Rat

A group of 32 male and female rats received betanin in their drinking water to a total dose of 17 g per animal. The mean life span was 845 days, the last animal dying at 1220 days. A group of 56 rats acted as controls. In the test group occurred 1 intraperitoneal sarcoma and 1 mammary fibro adenoma, in the controls 2 sarcomas and 2 fibro adenomata (Druckrey, 1959).

A group of 27 male and female rats received s.c. injections of betanin (concentration not stated) and a control group of 56 rats was also studied. The mean life span of the test animals was similar to that of controls at 800 days, the maximum life span 1250 days. The test animals developed 5 fibro adenomata of the breast and 2 unidentified tumours, the controls had 4 fibro adenomata of the breast, 1 renal adenoma, 1 sarcoma and 3 unidentified tumours (Druckrey, 1959).

Comments:

There is no information available on the metabolism of this naturally occurring betanin. The available long-term and reproduction studies are inadequate because only a few parameters were examined and many other essential observations have not been reported. No specific information is available on embryotoxicity including teratogenicity. This colour is, however, a normal constituent of food. Although the primary criteria are the same for evaluating the safety of food colours whether of natural or synthetic origin, consideration must be given to the quantities of food colour ingested as a result of technological use relative to its ingestion as an ingredient of food. This and the availability of an adequate specification permits evaluation in the absence of a full range of toxicological investigations.

EVALUATION

ADI not specified.*,**

FURTHER WORK OR INFORMATION

Required by June 1978

(a) metabolic studies preferably including man;

(b) adequate long-term study in one acceptable species.

REFERENCE

Druckrey, H. (1959) Personal communication

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* The statement "ADI not specified" means that, on the basis of the available data (toxicological, biochemical, and other), the total daily intake of the substance, arising from its use or uses at the levels necessary to achieve the desired effect and from its acceptable background in food, does not, in the opinion of the Committee,

represent a hazard to health. For this reason, and for the reasons stated in individual evaluations, the establishment of any acceptable daily intake (ADI) in mg per kg of body weight is not deemed necessary.

** Temporary.

See Also:
- Toxicological Abbreviations
- Beet red (WHO Food Additives Series 22)
- BEET RED (JECFA Evaluation)

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BEET RED AND BETANINE

EXPLANATION

Beet red is the colour obtained from the red beetroot, the principal component of which is betanine. This food colour was last reviewed at the twenty-sixth meeting of the Committee (Annex 1, reference 59), when the previously allocated temporary ADI "not specified" was withdrawn because the additional information required by the Committee at its eighteenth and twenty-second meetings was not available, that is, data on metabolism and long-term toxicity (Annex 1, references 35 and 47).

Since the previous evaluation, additional data have become available and are summarized and discussed in the following monograph.

BIOLOGICAL DATA

Biochemical aspects

Absorption, distribution, metabolism, and excretion

When betanine (4.5 µmole) was injected i.v. to rats, urinary excretion was rapid, 88% of the dose appearing in urine within 4 hours, and the plasma half-life was 32 minutes. Orally-administered betanine was poorly absorbed in rats and most of the dose was metabolized in the gastrointestinal tract; approximately 3% of the oral dose appeared in urine and a similar amount in faeces (Krantz et al., 1980).

Toxicological studies

Special studies on carcinogenicity

Rats

In a two-generation study, rats were given 50-78 mg betanine/kg b.w./day in drinking water throughout their lives. No evidence of carcinogenicity was reported (Druckrey, 1959).

No increase in tumours was observed in rats given repeated doses of betanine by subcutaneous injection (Druckrey, 1959).

A short-term study was performed to assess the ability of beet red to initiate or promote hepatocarcinogenesis in rats. Groups of female Sprague-Dawley rats (6-11 animals/group) were partially hepatectomized and treated with four different beet pigment preparations to assess their ability to initiate carcinogenesis; fermented betacyanin solution (50 mg/kg), pure betanine (50 mg/kg), degraded betanine (50 mg/kg), or a diet containing 2000 mg betacyanin/kg. N-Nitrosodiethylamine (10 mg/kg) was used in a positive control group. Another group previously initiated with N-nitrosodiethylamine was given a betacyanin solution (100 ppm, equivalent to 3.5 mg/rat/day) to determine the ability of betacyanin to promote carcinogenesis after initiation relative to control and phenobarbitone-pretreated rats. After 6 months (promotion studies) or 8 months (initiation studies) the livers were examined histologically and histochemically for gamma-glutamyl peptidase foci. There was no evidence that betalain preparations initiated or promoted hepatocarcinogenesis (Schwartz et al., 1983).

Special studies on mutagenicity

Beet red was found to be non-mutagenic against 5 strains of Salmonella typhimurium in the Ames test, with or without metabolic activation by S-9 preparations, at concentrations of 500-2500 µg/plate (von Elbe & Schwartz, 1981). At higher concentrations (50 mg/plate), beet red was reported to be weakly mutagenic against S. typhimurium, with or without metabolic activation (Ishidate et al., 1984).

No mutagenic activity was detected in studies using Escherichia coli or S. typhimurium assays, with or without metabolic activation by rat S-9 preparations, or intestinal microbial preparations. No DNA damage was detected in the E. coli rec assay (Haveland-Smith, 1981).

Beet red did not induce chromosomal aberrations in Chinese hamster fibroblast cells in culture (Ishidate et al., 1984).

Acute toxicity

Rats

No deaths were reported in rats given high oral doses of beetroot red (Druckrey, 1959).

Single doses of betanine injected i.v. into anaesthetised rats caused a transient increase in blood pressure and heart rate, the effect of 0.9 µmole betanine being about equivalent to that of 2 µmole adrenalin (Kranz et al., 1980).

Short-term studies

Rats

Groups of six rats were fed beet red preparations containing 2000 ppm betalains in the diet for 7 days. No significant differences were noted in body-weight gain, food intake, or gross pathological features relative to controls (von Elbe & Schwartz, 1981).

Long-term studies

(see "Special studies on carcinogenicity").

Observations in man

No information available.

COMMENTS AND EVALUATION

Previous Committees had considered beet red together with its major colour component, betanine. This Committee decided that it would be appropriate to evaluate these food colours separately and pointed out that, for the compound betanine, insufficient data were available to establish an ADI, since the information available to the Committee did not meet currently accepted standards.

In evaluating beet red, the Committee took into account the principles laid down by the Committee at its twenty-first meeting (Annex I, reference 44) and endorsed in Annex III of "Principles for the Safety Assessment of Food Additives and Contaminants in Food" (Annex 1, reference 76). Thus, when the concentrate is used to enhance the colour of beet products, it could be considered as food. If, on the other hand, the concentrate is used more generally as a colourant, careful specifications need to be established. Because nitrate is a component of beet red, it is necessary to ensure that levels of nitrate do not exceed the specifications. Under these conditions beet red could be used according to good manufacturing practice with an ADI

"not specified", keeping in mind the need to limit the nitrate content of foods produced for infants and young children.

REFERENCES

Druckrey (1959). Unpublished data submitted to WHO.

von Elbe, J.H. & Schwartz, S.J. (1981). Absence of mutagenic activity and a short-term toxicity study of beet pigments as food colourants. Arch. Toxicol., 49, 93-98.

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

Ishidate, M., Sofuni, T., Yoshikawa, K., Hayashi, M., Nohmi, T., Sawada, M., & Matsuoka (1984). Primary mutagenicity screening of food additives currently used in Japan. Fd. Chem. Toxicol., 22, 623.

Krantz, C., Monier, M., & Wahlstrom, B. (1980). Absorption, excretion, metabolism and cardiovascular effects of beetroot extract in the rat. Fd. Cosmet. Toxicol., 18, 363-366.

Schwartz, S.J., von Elbe, J.H., Pariza, M.W., Goldsworthy, T., & Pitot, H.C. (1983). Inability of red beet betalain pigments to initiate or promote hepatocarcinogenesis. Fd. Chem. Toxicol., 21, 531-535.

See Also:
Toxicological Abbreviations
Beet red (WHO Food Additives Series 6)
BEET RED (JECFA Evaluation)

Fat Free 6 oz. Strawberry Cheesecake

Serving Size 1 Container	
Amount Per Serving	
Calories 140	Calories from Fat 0
	% Daily Value*
Total Fat 0g	**0%**
Sat Fat 0g	**0%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 120mg	**5%**
Potassium 370mg	**11%**
Total Carbohydrate 29g	**10%**
Dietary Fiber 2g	**8%**
Sugars 26g	
Protein 7g	**14%**

Vitamin A 0%	Vitamin C 0%
Calcium 30%	Iron 0%
Thiamin 6%	Riboflavin 20%
Vitamin B6 4%	Vitamin B12 10%
Pantothenic Acid 6%	Phosphorus 20%
Magnesium 6%	

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

OUR FAMILY RECIPE: CULTURED PASTEURIZED NONFAT MILK, NATURALLY MILLED SUGAR, INULIN, STRAWBERRY JUICE FROM CONCENTRATE, NATURAL FLAVORS, PECTIN, BEET JUICE CONCENTRATE (FOR COLOR). CONTAINS: SIX LIVE ACTIVE CULTURES INCLUDING: L. ACIDOPHILUS, BIFIDUS, L. CASEI, AND L. REUTERI.

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Boca

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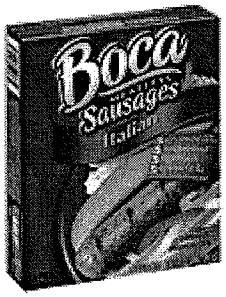
BOCA MEATLESS SAUSAGES ITALIAN



Ingredients: WATER, SOY PROTEIN ISOLATE, CANOLA OIL, TEXTURED SOY PROTEIN CONCENTRATE, EGG WHITES, POTATO STARCH, CONTAINS LESS THAN 2% SALT, WHEAT GLUTEN, SPICES, NATURAL FLAVOR (NON-MEAT), SUGAR, WASHED RAW SUGAR, MALT EXTRACT, PAPRIKA, DRIED GARLIC, SESAME OIL, BEET POWDER (COLOR).

Size: 10 oz
Upc: 5928360006

Nutrition Facts

Serving Size 71g
Servings per Container about 4

Amount Per Serving	
Calories 130	Calories from Fat 50
	% Daily Value*
Total Fat 6g	**9** %
Saturated Fat 0.5g	**3** %
Trans Fat 0g	
Cholesterol 0mg	**0** %
Sodium 650mg	**27** %
Total Carbohydrate 6g	**2** %
Dietary Fiber 1g	**4** %
Sugars 2g	
Protein 13g	

Vitamin A 2 %	Calcium 2 %
Vitamin C 0 %	Iron 8 %

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholest	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carb		300g	375g
Fiber		25g	30g

All Natural Raspberry Smoothie

Serving Size 1 Bottle 10 oz.
Amount Per Serving
Calories 240 Calories from Fat 25

	% Daily Value*
Total Fat 3g	**5%**
Sat Fat 2g	**10%**
Trans Fat 0g	
Cholesterol 10mg	**3%**
Sodium 150mg	**6%**
Potassium 510mg	**15%**
Total Carbohydrate 45g	**15%**
Dietary Fiber 4g	**16%**
Sugars 41g	
Protein 10g	**20%**

Vitamin A 2%	Vitamin C 0%
Calcium 40%	Iron 0%
Thiamin 8%	Riboflavin 30%
Vitamin B6 4%	Vitamin B12 15%
Pantothenic Acid 8%	Phosphorus 30%
Magnesium 8%	

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

OUR FAMILY RECIPE: CULTURED PASTEURIZED LOW FAT MILK, NATURALLY MILLED SUGAR, INULIN, RASPBERRY PUREE, NATURAL FLAVOR, PECTIN, CARROT AND BEET JUICE CONCENTRATES (FOR COLOR). CONTAINS: SIX LIVE ACTIVE CULTURES INCLUDING L. ACIDOPHILUS, BIFIDUS, L. CASEI, AND L. REUTERI.

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MATERIAL SAFETY DATA SHEET

Date issued: April 19, 2006

DBB-10

Emergency Phone Number: 262/268-7272

Product

Name:	DBB-10
Active ingredient:	Betanin, approx. 1.0%
Description:	Red Beet Concentrate, Water
Intended use:	Food color

Chemical and physical properties

Appearance	Bright Red flowing liquid
Density, g/ml	1.30-1.35
Total Solids	67.5 +/- 2.5%
Vapor Density (Air=1):	N/A
Melting point, °C	
Boiling point, °C	
Solubility:	Dispersible in water

Product handling

Storage:	Tightly sealed at 1-4°C (34-40°F)
Handling:	Protect container from physical damage

Fire, explosion and reactivity data

Flash point, °F:	N/A
Extinguishing media:	Carbon dioxide, dry chemical, water
Special fire-fighting procedures:	None known.
Unusual fire or explosion hazard:	None known.

Stability

Materials to avoid:	none known
Conditions to avoid:	none known
Hazardous decomposition products:	burning may yield CO and $C0_2$
Hazardous polymerization products:	will not occur

D.D. Williamson Colors, LLC
815 Sunset Road
Port Washington, WI 53074
Phone (262) 268 7272

Health hazards

Skin contact:	May cause temporary staining.
Eye contact:	May cause irritation
Inhalation:	May cause irritation
Ingestion:	May cause irritation
Toxicological Data:	N/A

First aid procedures

Skin:	Wash with soap and water
Eyes:	Flush eye with water immediately, remove contact lenses before flushing, seek medical attention
Inhalation:	
Ingestion:	If irritation occurs, seek medical attention

Personal protection

Eyes:	Protective glasses
Skin:	Gloves to prevent staining
Respiratory:	Normally none needed
Ventilation:	Normal

Spill, leak and disposal procedures

Spill:	Rinse area with water
Waste disposal:	Contact local authorities
Ecology:	Degradable in the environment

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MATERIAL SAFETY DATA SHEET

Date issued: August 25, 2006

DBI-05

Emergency Phone Number: 262/268-7272

Product

Name:	DBI-05
Active ingredient:	Betanin, approx. 0.5%
Description:	Red Beet Concentrate, Maltodextrin
Intended use:	Food color

Chemical and physical properties

Appearance	Bright Red flowing liquid
Density, g/ml	N/A
Total Solids	N/A
Vapor Density (Air=1):	N/A
Melting point, °C	N/A
Boiling point, °C	N/A
Solubility:	Dispersible in water

Product handling

Storage:	Tightly sealed at 1-4°C (34-40°F)
Handling:	Protect container from physical damage

Fire, explosion and reactivity data

Flash point, °F:	N/A
Extinguishing media:	Carbon dioxide, dry chemical, water
Special fire-fighting procedures:	None known.
Unusual fire or explosion hazard:	None known.

Stability

Materials to avoid:	none known
Conditions to avoid:	none known
Hazardous decomposition products:	burning may yield CO and $C0_2$
Hazardous polymerization products:	will not occur

D.D. Williamson Colors, LLC
815 Sunset Road
Port Washington, WI 53074
Phone (262) 268 7272

Health hazards

Skin contact:	May cause temporary staining.
Eye contact:	May cause irritation
Inhalation:	May cause irritation
Ingestion:	May cause irritation
Toxicological Data:	N/A

First aid procedures

Skin:	Wash with soap and water
Eyes:	Flush eye with water immediately, remove contact lenses before flushing, seek medical attention
Inhalation:	
Ingestion:	If irritation occurs, seek medical attention

Personal protection

Eyes:	Protective glasses
Skin:	Gloves to prevent staining
Respiratory:	Normally none needed
Ventilation:	Normal

Spill, leak and disposal procedures

Spill:	Rinse area with water
Waste disposal:	Contact local authorities
Ecology:	Degradable in the environment

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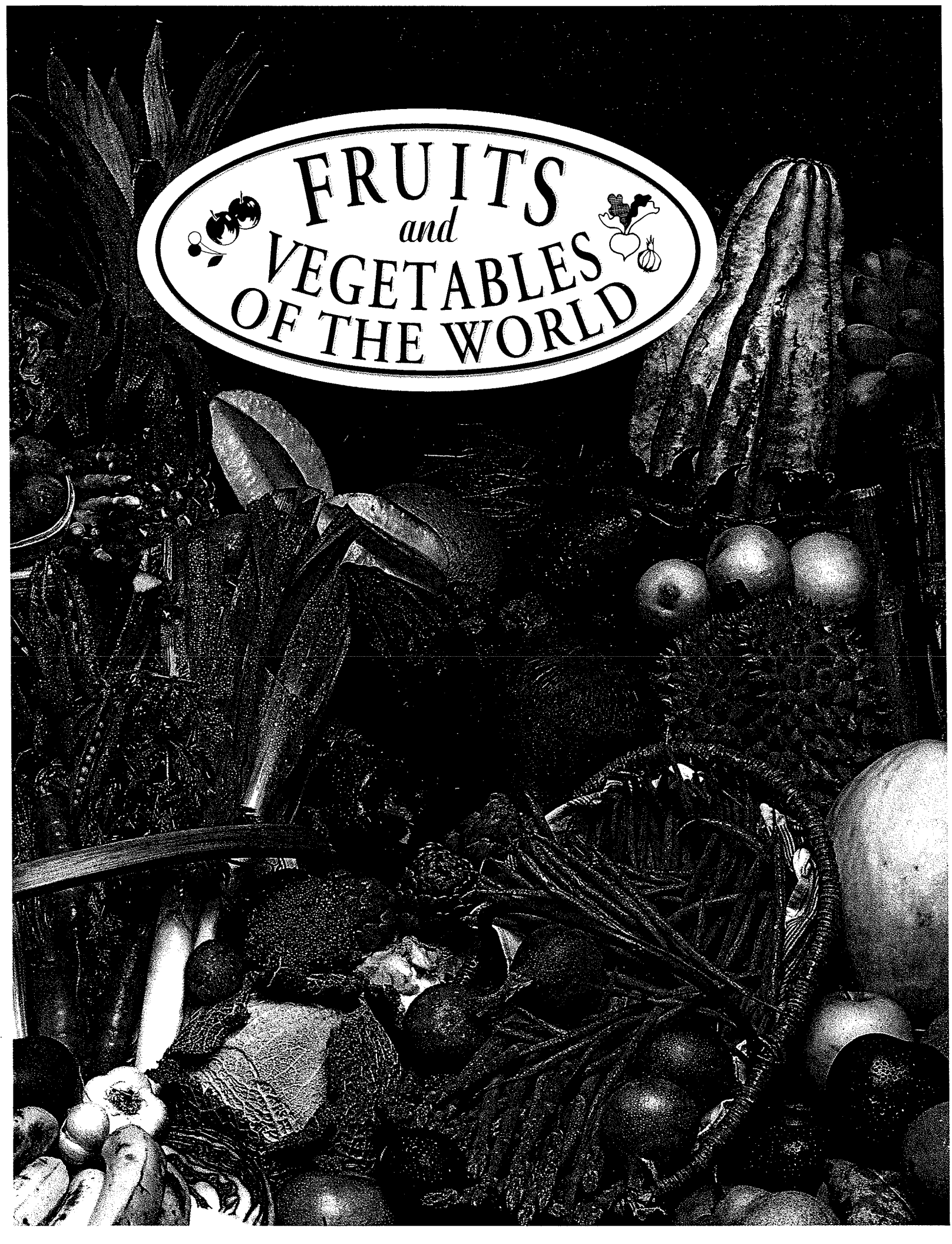
FRUITS
and
VEGETABLES
OF THE WORLD

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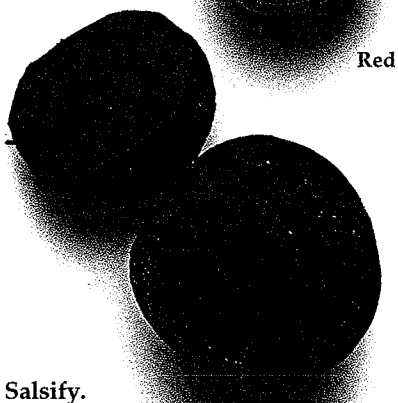
Eggplants, salsify, and red beet

Eggplant. Although eggplant was eaten four thousand years ago in its native land, India, this vegetable did not find its way into our kitchens until the end of the nineteenth century. Large or small, purple or white, round or long, eggplants are fresh when their skin is smooth and shiny, and their thorny peduncle inflated with sap. The small ones have a mild pulp that melts in the mouth without a single trace of bitterness. It is best to cut the larger ones into slices and sprinkle them with salt then let them stand, a process which draws out the bitter juices and reduces the vegetable's absorption capacity. This should save you from suffering the same fate as the poor Imam Bayildi. According to legend, the Imam married a young girl who was renowned for her great skill in preparing eggplants. As a dowry, he requested twelve jars of olive oil, but by the eleventh day of their marriage, all the oil had been used up (eggplants absorb oil until saturation point). Upon discovering this, the Imam dropped dead, either because he was saturated with oil or with shock at the disappearance of the dowry. The recipe outlived him, however, and to this day Oriental restaurants continue to serve a dish of fried egg-plant called "Imam Bayildi."

Red beet



Salsify

Salsify. Wild salsify has long been eaten around the Mediterranean basin. The Greeks referred to it as "the billy goat's beard," a reference to the silky filament that adorns the seed. The British found that salsify had such a special flavor that they decided to call it an oyster plant. The real, brown-skinned salsify is increasingly rare: it is being replaced by the black-skinned version. Italians call it *scorza nera*, or black bark. It's best to select the straightest looking salsifies as they are easier to peel. If the root is too fat, the chances are the vegetable will be hollow. Gloves should be worn when preparing salsify because it secretes a latex that dirties the hands. The peeled roots should be immediately placed in cold water to which lemon juice or vinegar has been added, in order to avoid oxidation. Cook in salted boiling water for an hour. Adding milk to the cooking water will make salsify tender and turn them a whitish color.

Red beet. The Romans called this vegetable *beta* because its stem bends as it grows, drawing a loop that looks like the Greek letter β (beta). This vegetable is the result of improvements on a wild seaside plant (*Beta maritima*), which has yielded other vegetables like Swiss chard and sugar beet. Most red beet roots are sold cooked, but they are also delicious raw, grated, or cut into fine strips.

Eggplant