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January 15,, 2007

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

ORIGINAL

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.

**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: Lycopene, the extract from the oils of *solanaceae solanum lycopersicum* (family, genus, species). This agricultural substance is also commonly known as "tomato extract."

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

2.1 LycoRed Ltd.  
PO Box 320  
Beer-Sheva 84102  
Israel  
011-972-8-629-6994

2.2 Kalsec, Inc.  
PO Box 50511  
Kalamazoo, MI 49005-0511  
United States  
(269) 349-9711

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3. The intended or current use of the substance: Lycopene is used as a natural color additive in baked goods, beverages, candies, 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 lycopene 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, lycopene 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: Lycopene develops a red to light orange 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 carotenoid molecules in the tomatoes.

5. The source of the substance and a detailed description of its manufacturing or processing procedures: Tomatoes grow on vines throughout the world. The tomatoes are collected, cut, and crushed into small pieces, which are physically ground against one another in vegetable oil. The oil is filtered and concentrated, producing a dark, viscous, red liquid concentrate composed of the same carotenoid molecules produced inside the tomatoes.

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 lycopene are known; but carotenoids in general (particularly from carrots) have been used since antiquity to color human food. Carotenoids are therefore Generally Regarded As Safe (GRAS).

7. Information regarding EPA, FDA, and State Regulations: FDA permits the use of lycopene as a color additive exempt from certification. 21 CFR 73.30 Carrot Oil. Lycopene is also permitted as a natural color additive in foods in the European Union (E160(d)) and throughout Asia.

8. The Chemical Abstract Service (CAS) number: There exists a specific CAS Number for beta-carotene. It is 1393-63-1. Further, carotenoids in general have been assigned CAS No. 7235-40-7.

9. The substance's physical properties and chemical mode of action: The carotenoids extracted from tomatoes / tomato oil are distinct and unique molecules. They are different from anthocyanins and betalains (other molecules used as natural color-ants). Carotenoids are sensitive to light and heat, degrading rapidly under high heat and/or direct sunlight. In addition, carotenoids display very strong antioxidant properties which now appear beneficial to human health. Beyond these unique properties, carotenoids do not interact with substances used in organic food production and have no impact on the environment.

Tomatoes 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). Tomatoes, and the carotenoids extracted from tomatoes, are GRAS.

11. Research information about the substance: See the attached Bibliography. There are several leading researchers on carotenoids in the US including Carol Locey (Kalsec, Inc.), Minhthy L. Nguyen (formerly of Ohio State University, Columbus), and Steven J. Schwartz (Ohio State University, Columbus).

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, lycopene inside cut tomatoes, 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 lycopene at 0.5% of the formula. They do not actively seek out organic certified lycopene 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 lycopene 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 tomatoes (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.

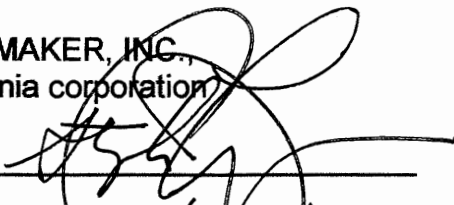
Because there is no current supply of organic certified natural colorants from International sources, and because there is no current supply of organic certified natural colorants from US sources, and because natural colorants at levels below 5% greatly improve the visual appearance of organic foods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

13. This Petition respectfully seeks the addition of lycopene, a.k.a. "tomato extract," to the National List as a non-organic agricultural product under Section 205.606 of the NOP.

Respectfully Submitted,

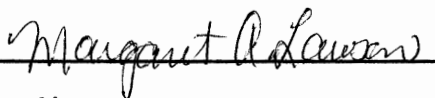
COLORMAKER, INC.,  
a California corporation

By:

  
\_\_\_\_\_  
Stephen J. Lewis  
(Name & Title)

DD WILLIAMSON, INC.  
a Kentucky corporation

By:

  
\_\_\_\_\_  
Margaret A. Lawson  
(Name & Title)  
VP Science & Innovation

ColorMaker, Inc.  
3309 East Miraloma Ave., Suite 105  
Anaheim, California 92806  
(714) 572-0444  
(714) 572-0999 fax

*inquire@colormaker.com*

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 Lycopene Extract
- 1.2 Product Number: 2743C
- 1.3 Ingredient Statement: Lycopene
- 1.4 Description of Product: A red liquid designed to color and function in fat & oil-based food 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	N/A
9.5	Solubility in Water	NONE; soluble in oil
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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Dean, Jenny, Wild Color; Watson – Guptill, Publishers, Copyright 1999.

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Greenfield, Amy Butler, A Perfect Red; Harper Collins, Publishers; Copyright 2005.

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**EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST**

**Category 1. Adverse impacts on humans or the environment?**

Substance – LYCOPENE

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 – LYCOPENE

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 – LYCOPENE

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.