

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: Red corn colorant, a vegetable juice extract of red corn kernels from *Gramineae Zea Mays* (family, genus, species).
2. The producer's name, address and telephone number: There is only one producer of the red corn colorant.

2.1 Suntava, LLC
3290 S St Croix Trail
P.O. Box 268
Afton, MN 55001
United States
651-998-0723

3. The intended or current use of the substance: Red corn colorant is used as a natural color additive in dairy and non-dairy beverages, yogurts, confectionary, soups and sauces, desserts, jams and jellies, fruit filling, pet food products, snack products, cereals, powdered meal formulations, cosmetics, and compressed tablets as well as any other applications that requires a red colorant. Red corn colorant qualifies as a vegetable juice color under FDA 21 CFR 73 guidelines.

The use of red corn colorant as a natural color additive supports the organic philosophy and promotes the use of organic food and beverage products for many reasons. Red-yellow is one of the most desirable and widely used colors in food products. Red corn colorant uses a natural non-genetically modified and regional agricultural crop. Natural dyes, such as our red corn colorant, improve the sensorial characteristics of organic food and beverage products that otherwise may a) rely on synthetic alternatives such as FD&C Red #40 or b) be formulated without the improved visual characteristics derived from a natural red colorant.

Furthermore, the use of a product derived from a high-yield and reliable domestic crop, such as the red colorant from red corn, is a perfect match for the original organic rationale that promotes organic products to enhance the local economy and lifestyle of local growers. That promotion is further supported by the non-genetically modified nature of the crop from which the red corn colorant is derived.

4. A list of handling activities for which the substance will be used: Red corn colorant ranges from a bright red to purple color in organic food and beverage products, depending upon the pH of the finished product. Its color has a reddish-yellow hue that resembles FD&C Red #40. The red corn colorant is used to

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enhance the visual characteristics of the product and to maximize their visual-sensorial attributes. The red to purple color range seen in the red corn colorant is a function of the presence of naturally-occurring anthocyanins in the product. Anthocyanins are responsible for the red, purple, and blue colors of many fruits, vegetables, cereal grains, and flowers.

5. The source of the substance and a detailed description of its manufacturing or processing procedures: *Zea mays* is known as maize throughout most of the world, and as corn in the United States. It is a large, annual and monoecious grass that is grown for a wide variety of uses. Corn as a plant is the premier cash crop in the United States, and its cultivation, genetics, processing, and distribution on a national and international scale are widely understood. Red corn is a member of that grass family with its individual characteristic of high anthocyanin content.

The red natural colorant is a vegetable juice extracted from the red corn kernels.

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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 have been found specifically on red corn colorant. However, anthocyanins have been widely used in the food and beverage industry some of which have been certified as GRAS (Generally Regarded As Safe). Likewise, corn products derived from corn kernels have been widely used for human consumption.
7. Information regarding EPA, FDA and State Regulations: The use of red corn colorant as a color additive is permitted by the FDA under the 21 CFR 73.260 for vegetable juice production. Similar colorants from other fruits and vegetables sources are also approved in the European Union (EU, E163) as well as throughout Asia and the Americas.
8. The Chemical Abstract Service (CAS) number: There is no specific CAS number for the red corn colorant. However, anthocyanins in general have been assigned the CAS no. 11029-12-2 for grape skin extract. There is also a CAS no. for each specific anthocyanin found in the red corn colorant (such as CAS no. 528-58-5 for cyanidin , CAS 134-01-0 for peonidin and CAS no.134-04-3 E163 for pelargonidin).
9. The substance's physical properties and chemical mode of action: The anthocyanin pigments found in the red corn colorant are the same ones found in

the red corn kernels. The basic physical structure of an anthocyanin is a flavylum cation. Anthocyanins are mostly comprised of 3-glucoside sugars, though many linkages are found in nature.

Red corn colorant anthocyanins show high solubility in water and sensitivity to pH, high temperature and light. Their color changes from bright red to purple in acidic to near neutral. Anthocyanins found in the red corn colorant have side chains that render them more stable than anthocyanin from other sources.

Anthocyanins also possess free-radical scavenging capabilities. Literature shows that these antioxidant properties may be beneficial for human health. Red corn anthocyanins offer sensory benefits to the organic food and beverage products without any detrimental effects to the products themselves or to the environment.

10. Safety information about the substance: See attached Material Safety Data Sheet (MSDS). The red corn extract is currently in the process of obtaining GRAS certification. Red corn colorant qualifies as a vegetable juice color under FDA 21 CFR 73 guidelines.
11. Research information about the substance: See the attached bibliography on anthocyanins as well as on corn. The anthocyanins found in the red corn colorant are the same found in the red corn kernels. Anthocyanins have been widely used in the food and beverage industry. Literature research indicates that anthocyanins have no detrimental effect on human health or the environment.

12. Justification Statements:

Suntava is committed to producing a proprietary red corn used to make an organic red colorant that can be commercially available. We have identified the obstacles in providing such a product that is consistent in its quality and available in production quantities, which we are working determinedly to resolve.

While there is an ongoing effort to develop certified organic colors for organic food processing, some sources of natural colors are more difficult to produce organically, especially when considering the quality, quantity, and form that organic processors require.

We have identified 3 key obstacles for growing an organic red corn that will reliably produce the plant pigment needed. We are actively working to resolve each obstacle so that we can produce a viable organic alternative to be used to make a red food colorant.

We have evaluated many red and purple corn varieties that may be grown broadly, but none of these varieties produce the color performance in the

quantities desired by our customers. However, we do know that Suntava's proprietary red corn provides the quality and quantity of red pigment producing anthocyanins needed to make the red colorant.

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Obstacle #1 – Developing a Viable Organic Hybrid

Suntava has invested over 12 years in the development of a non-GMO hybrid that yielded an agronomic crop containing the anthocyanin needed to make red food colorant. While Suntava has already worked through a majority of the issues necessary to produce this hybrid considering non-organic conditions and handling, we are now attempting to prove the viability of the red corn hybrid considering organic conditions.

In addition to the known factors that needed to be addressed when developing the hybrid, producing the organic seed and growing an organic crop will introduce additional considerations.

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Thus, it is important to understand how the crop performs in any new condition prior to planting production acreage. This year, we have just begun testing our hybrid in organic soils in southern Minnesota.

When the crop is ready, we will analyze its agronomics, anthocyanin yields, and the performance of the colorant derived from the crop. Depending on the results of this analysis, we may have to produce a special hybrid for organic conditions.

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Although we hope for the best results from the test plot, we also recognize that there are many potential failure points in this process. Producing a specialty corn hybrid that not only has good agronomics and pest resistance, but also yields the specific anthocyanin producing red pigment has been very challenging.

Obstacle #2 – Production Quantity of the Hybrid Seed

In addition to the factors mentioned above that impact the development of an organic hybrid we also need to be able to produce enough seed for growers. The challenges here are two-fold: 1) We must first understand how the current hybrid performs in organic conditions and 2) If it indeed performs and produces the

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quality and quantity expected, we will have to expand the current hybrid seed considering all of the organic requirements.

Obstacle #3 – Recruiting Organic Growers

Once we have validated an organic hybrid that will produce a crop and colorant that is viable and the seed is available in production quantities, we then need to ensure we have sufficient organic growers to produce the amount of red corn needed to establish a reliable supply chain.

As a result, growers are cautious about its ability to produce equal to or better revenue relative to yellow corn as well as its potential impact on neighboring crops and their soils.

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If it were to be grown in other geographic areas with different soils and climate conditions, both the yields and the red pigment producing anthocyanin will vary. This variability will not only have an effect on the consistency of the color performance, but also the quantity of the anthocyanins produced. Currently, we are testing the viability of growing the red corn hybrid in other geographic regions of the country and of the world. However, we are too early into this study to conclude any useful results.

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This presents a challenge in recruiting sufficient growers, as there are significantly fewer organic growers when compared to non-organic growers. In fact, there are only 592 organic growers in the entire state of Minnesota compared to 79,000 non-organic growers. Of those 592 organic farmers, hundreds have cattle and dairy operations and others supply produce for farmers' markets, in turn further reducing the number of available organic farmers.

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Furthermore, many organic growers have relatively small operations and are cautious of unproven crops because of the relative impact each crop has on their livelihood. In short, although more difficult, we believe we will be able to recruit organic growers when we can show them that the specialty crop we are asking them to plant has a history of reliable performance and will not negatively impact their overall operation's viability.

Petitioner's Conclusion

Until we are able to fully resolve these issues and are able to make an organic form commercially available, we respectfully submit this petition for red corn colorant to be added to the National List as a non-organic agricultural product under Section 205.606 of the NOP.

Respectfully Submitted,

Suntava, LLC
A Delaware Limited Liability Company

By: _____

Its: _____

Bibliography

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USDA Publication on Corn
(<http://www.aphis.usda.gov/brs/corn.html>)



MATERIAL SAFETY DATA SHEET

SAYELA™ COLORANT

Test Sample

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name Sayela™ Colorant	Contact Information Suntava, LLC 1246 University Ave. W Suite #333 St. Paul, MN 55104 Phone: 651.998.0723 Fax: 651.998.0735 Email: sales@suntava.com
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SECTION 2: COMPOSITION AND INGREDIENTS

Ingredients: Suntava™ Red Maize extract, water, dilute citric acid

SECTION 3: HAZARD IDENTIFICATION

The material is not defined as hazardous under the definition of hazardous material defined in the Occupational Safety and Health Administration (OSHA) Hazardous Communication Rule, given in 29 CFR §1910.1200.

SECTION 4: FIRST AID MEASURES

Eye Contact:	Flush eyes with water for 15 minutes. Seek medical attention if symptoms occur.
Skin Contact:	Flush with water or soap for 15 minutes or until all traces have been removed. Seek medical attention if symptoms persist. Product may dye skin temporarily.
Inhalation:	Product may cause irritation to nose and throat. If inhaled, move to fresh air. Seek medical attention if symptoms persist.
Ingestion:	Product is not known to cause serious health effects. If swallowed, rinse mouth and throat with water. Drink water. Seek medical attention if symptoms occur.

SECTION 5: FIRE FIGHTING MEASURES

Flammability:	Product is not combustible
Extinguishing Media:	Product is not flammable. Use appropriate media for materials actually involved in fire.
Special Fire Fighting Procedures:	None
Unusual Fire & Explosion Hazards:	None

SECTION 6: ACCIDENTAL RELEASE MEASURES

Leak and Spill Procedures:	Contain material spilled. Flush spill area with water. Material on wet floor may be slippery.
Personal Precautions:	See Section 4: First Aid Measures
Environmental Precautions:	None

SECTION 7: HANDLING AND STORAGE

Handling Procedures:	No specific equipment required.
Hygiene Practices:	Follow food GMP's. Avoid contact with skin, eyes and clothing. After handling this product, wash hands before eating or drinking.
Storage:	Store in cool dark place. Refrigerated temperature is recommended. If bottle is opened, use immediately or refrigerate. Mix well prior to use.

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Engineering Controls:	Provide adequate ventilation. Eyewash fountains and safety showers should be easily accessible.
Respiratory Protection:	Use good ventilation. Respirator not required.
Protective Gloves:	Minimize skin contact. Wear gloves for extended or repeated skin contact with concentrate.
Eye Protection:	Avoid eye contact and wear safety glasses while in the laboratory.
Clothing:	Standard work clothing.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Dark red - purple liquid	Boiling Point: >100°C
Odor: Characteristic	Freezing Point: N/A
pH: 3.0 - 4.0	Melting Point: N/A
Solubility in Water: Soluble	Specific Gravity: N/A



SECTION 10: STABILITY AND REACTIVITY

Chemical Stability: Stable.

Materials to Avoid: None known.

Incompatible Materials: None known.

Hazardous Decomposition or Byproducts: None known.

SECTION 11: TOXICOLOGICAL INFORMATION

No known toxic effects.

SECTION 12: ECOLOGICAL INFORMATION

No known environmental impact. Product is biodegradable.

SECTION 13: DISPOSAL INFORMATION

According to local, state or federal regulations.

SECTION 14: TRANSPORTATION INFORMATION

Non-hazardous.

SECTION 15: REGULATORY INFORMATION

Under regulations by the Food and Drug Administration (FDA).

SECTION 16: OTHER INFORMATION

HMIS® Health: 0 Flammability: 0 Reactivity: 0

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