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RECEIVED  
USDA NATIONAL  
ORGANIC PROGRAM

2007 JUL 10 10:10

07/08/07

TO: Mr. Robert Pooler  
Agricultural Marketing Specialist  
National Organic Program

FROM: David L. Tuescher  
Technical Director

DATE: July 03, 2007

RE: Petition to include Caramel Color in the Allowed List for use in Organic Products

Dear Sir,

Sethness Products Company currently produces two liquid and one powdered Organic Caramel Color. Unfortunately, these three products are not acceptable in all applications. Caramel Colors vary in ionic charge, salt solution solubility, alcohol solubility, and many other characteristics. Sethness Products Company currently makes about sixty liquid and 20 powdered Caramel Colors. Therefore we are requesting the inclusion of non-organic Caramel Color in the list of non-organic agricultural substances allowed in or on processed products labeled as "organic" (205.606).

This petition follows the steps outlined in the Federal Register Vol. 72, No. 11 Thursday, January 18, 2007 7 CFR Part 205.

1. There is no chemical name; the common name for this product is "Caramel Color". The first attachment to this petition is a copy of CFR 21 73.85. This document defines the identity of Caramel Color and the constituents acceptable for use in manufacturing Caramel Color. It also lists the general specifications. Please note the bottom statement - 182.1235. Caramel Color is generally recognized as safe.
2. The manufacturer is Sethness Products Company located at 1347 Beaver Channel Parkway Clinton, Iowa 52732. The primary contacts are Lloyd R. Glanz (Plant Manager) or David L. Tuescher (Technical Director). The phone number is 563-243-3943.
3. Caramel Color is primarily used as a coloring agent. It also has secondary uses for taste, mouth feel, pH, emulsification and various other characteristics.
4. Caramel Color is used in many food applications. A short list includes: carbonated drinks, non-carbonated drinks, breads, meats, cereals, alcoholic drinks, etc. The use level varies from less than 0.1% to greater than 20%. Caramel Color is added to the batch at various times depending on the customers' process. Caramel Color does not react in any way with the products but is simply an additive

5. The starting material for Caramel Color is one of the carbohydrates listed in the CFR (see attachment). Depending on Caramel Color type, one or more of the chemicals listed in the CFR are added and the mixture is cooked in either an atmospheric kettle or a pressure kettle. The pressure kettles allow the mixture to reach higher temperatures with less loss of water (this means lower viscosity). The process is monitored for color strength by using a visible light spectrophotometer. As the process progresses, the simple sugars form polymers that are the source of the color. This process is equivalent to what a household cook would do on a stove except we have much larger volumes. When the target color is reached, the mass is cooled. In an open atmospheric reactor, water is added for cooling. The mass in the pressure reactors is cooled by flashing the mass into a large atmospheric vessel. The drop in pressure allows a significant portion of the water to evaporate. This evaporation is the source of the cooling. While still fairly hot, the Caramel Color is passed through a filter to remove any carbon or other solid material that may have formed during the cook. The material is then passed through a heat exchanger to further cool the product. When the product is in the final tank QC takes a sample and checks it against specifications. At this point small corrections can be made to bring the product into specifications. For example: Ammonia can be added to increase the pH, and water can be added to reduce the specific gravity. When the material meets specifications, a lot number is assigned, and the lot is available for sale.

6. The Three organic products have been reviewed by the Iowa Department of Agriculture and Land Stewardship, and certified as "organic". The other Sethness Products Company Caramel Colors have not been reviewed.

7. References:

FEMA Number 2235

FDA References:

Standard	21 CFR 73.85
GRAS	21 CFR 182.1235
GRAS for Feed	21 CFR 582.1235
Drug use	21 CFR 73.1085
Cosmetics	21 CFR 73.2085

8. The CAS Number is 8028-89-5

9. a. Caramel Color is a water soluble liquid or solid with a pH that ranges from 2 to 10. Other than color, pH and ionic charge, it has no known reactions with other food products. Caramel Colors vary in ionic charge from positive to neutral to negative. Mixing a negative Caramel Color with a positive ion in a product will generate a haze or precipitate.

b. I have seen no data on environmental persistence and toxicity. This product is equivalent to that produced in home kitchens for as long as people have been cooking.

c. Once again, I have seen no data on environmental impacts. The manufacturing plant is very environmentally conscious. Environmentally conscious and cost control typically go hand in hand.

d. Caramel Color was studied extensively about thirty years ago. A copy of the contents page of the "Safety Evaluation Studies on Caramel Color" Food and Chemical Toxicology Volume 30 number 5 published in May of 1992 is attached. Full copies are available upon your request.

e. Once again, I have not seen any data on the effects Caramel Color will have on soil organisms, crops or livestock. Our products did participate in a feeding study with dogs. The animals preferred food colored with Caramel Color to that colored with FD&C colors.

10. MSDS sheets for both the liquid and powdered Caramel Color are attached. I am not aware of any studies from the National Institute of Environmental Health.

11. I am not aware of any research concerning Caramel Color other than the tox studies cited above.
12. G. Inclusion of a Non-Organically Produced Agricultural Substance onto the National List 205.606 – Currently, Sethness Products Company produces about 60 different liquid and 20 different powdered Caramel Colors. The large number of products is due to the many varied uses of Caramel Color. While we have produced two liquid and one powdered Organic Caramel Colors, these products cannot meet all the varied needs of our customers. It would be cost prohibitive to try to develop products for every need. Therefore we are petitioning to allow the use of non-organic Caramel Color when there is no Organic product that is acceptable for use.

# Code of federal regulations

## Food and Drugs

21

PARTS 1 TO 99  
Revised as of April 1, 1994



### § 73.85 Caramel.

(a) *Identity.* (1) The color additive caramel is the dark-brown liquid or solid material resulting from the carefully controlled heat treatment of the following food-grade carbohydrates:

Dextrose.  
Invert sugar.  
Lactose.  
Malt sirup.  
Molasses.  
Starch hydrolysates and fractions thereof.  
Sucrose.

(2) The food-grade acids, alkalis, and salts listed in this subparagraph may be employed to assist caramelization, in amounts consistent with good manufacturing practice.

(i) *Acids:*

Acetic acid.  
Citric acid.  
Phosphoric acid.  
Sulfuric acid.  
Sulfurous acid.

(ii) *Alkalis:*

Ammonium hydroxide.  
Calcium hydroxide U.S.P.  
Potassium hydroxide.  
Sodium hydroxide.

(iii) *Salts:* Ammonium, sodium, or potassium carbonate, bicarbonate, phosphate (including dibasic phosphate and monobasic phosphate), sulfate, and sulfite.

(3) Polyglycerol esters of fatty acids, identified in § 172.854 of this chapter, may be used as antifoaming agents in amounts not greater than that required to produce the intended effect.

(4) Color additive mixtures for food use made with caramel may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* Caramel shall conform to the following specifications:

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 0.1 part per million.

(c) *Uses and restrictions.* Caramel may be safely used for coloring 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 added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 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.

### § 182.1235 Caramel.

(a) *Product.* Caramel.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

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**MATERIAL SAFETY DATA SHEET  
POWDERED CARAMEL COLOR**

Sethness Products Company  
1347 Beaver Channel Parkway  
Clinton, Iowa 52732-5933 USA  
Telephone: 563/243-3943  
e-mail: [sethness@revealed.net](mailto:sethness@revealed.net)

Date Prepared:  
September 1, 2005

**SECTION 1. - CHEMICAL IDENTIFICATION**

- ❖ Name: Caramel Color
- ❖ CAS #: 8028-89-5 EEC #: E150

**SECTION 2. - COMPOSITION /INGREDIENT INFORMATION**

- ❖ Caramel Color 100%
- ❖ GRAS for Human Consumption - 21 CFR 73.85, 21 CFR 182.1235

**SECTION 3. - HAZARDS IDENTIFICATION**

- ❖ Nuisance Particulate, 15 MG/M<sup>3</sup> of total dust. or 5 MG/M<sup>3</sup> respirable dust.
- ❖ This material, like most powdered agricultural products, is capable of creating a dust explosion. Powdered Caramel Color is a CLASS I dust hazard and is less hazardous than dry starch (CLASS II).

**SECTION 4. - FIRST-AID MEASURES**

- ❖ In case of eye contact, immediately flush eyes with water for at least 15 minutes.
- ❖ In case of skin contact, wash skin with soap and water.

**SECTION 5. - FIRE FIGHTING MEASURES**

- ❖ No special requirements.

**SECTION 6. - ACCIDENTAL RELEASE MEASURES**

- ❖ Spillage should be swept up as much as possible. If cleaning with water is necessary, washings should be disposed of in a sanitary sewer as product contains some BOD (Biological Oxygen Demand) loading.
- ❖ Secondary containment may be accomplished by diking using the material mentioned above or sorbent pillows and dikes.

**SECTION 7. - HANDLING AND STORAGE**

- ❖ Store in closed containers in cool and dry environment, preferably not to exceed 33°C.
- ❖ High temperature storage accelerates product degradation although product remains non-hazardous.

**SECTION 8. – EXPOSURE CONTROLS/PERSONAL PROTECTION**

- ❖ No special precautions necessary. Normal hygiene practices.

**SECTION 9. – PHYSICAL AND CHEMICAL PROPERTIES**

- ❖ Appearance and Odor: Blackish brown solid with burnt sugar odor and taste.
- ❖ Readily absorbs moisture from the air.
- ❖ Solubility in Water: Complete

**SECTION 10. – STABILITY AND REACTIVITY**

- ❖ No known hazardous incompatibilities.

**SECTION 11. – TOXICOLOGICAL INFORMATION**

- ❖ No known acute or chronic health hazards.

**SECTION 12. – ECOLOGICAL INFORMATION**

- ❖ May contribute to Biochemical Oxygen Demand (BOD) and Chemical Oxygen Demand (COD).

**SECTION 13. – DISPOSAL CONSIDERATIONS**

- ❖ Conventional methods consistent with local, state and federal regulations.

**SECTION 14. – TRANSPORT INFORMATION**

- ❖ Listed under “CAMEL” or “BURNT SUGAR”
- ❖ NAFTA Harmonized Tariff Classification Code: 1702-90-5000
- ❖ No hazardous or special markings required.

**SECTION 15. – REGULATORY INFORMATION**

- ❖ U.S. Code of Federal Regulations: Title 21 – Food and Drugs Section 73.85 (CAMEL), Section 182.1235 (GRAS).
- ❖ Food Chemicals Codex, “CAMEL”.
- ❖ European Directives: 94/36/EC and 95/45/EC

**SECTION 16. – OTHER INFORMATION**

- ❖ The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide.

**MATERIAL SAFETY DATA SHEET**  
**LIQUID CARAMEL COLOR**

Sethness Products Company  
1347 Beaver Channel Parkway  
Clinton, Iowa 52732-5933 USA  
Telephone: 563/243-3943  
e-mail: [sethness@revealed.net](mailto:sethness@revealed.net)

Date Prepared:  
September 1, 2005

**SECTION 1. - CHEMICAL IDENTIFICATION**

- ❖ Name: Caramel Color
- ❖ NFPA Rating: Health-0, Flamability-1, Reactivity-0

**SECTION 2. - COMPOSITION/INGREDIENT INFORMATION**

- ❖ Caramel Color 100%
- ❖ CAS #: 8028-89-5 EEC #: E150
- ❖ GRAS for Human Consumption -- 21 CFR 73.85, 21 CFR 182.1235

**SECTION 3. - HAZARDS IDENTIFICATION**

- ❖ None

**SECTION 4. - FIRST-AID MEASURES**

- ❖ In case of eye contact, immediately flush eyes with water for at least 15 minutes.
- ❖ In case of skin contact, wash skin with soap and water.

**SECTION 5. - FIRE FIGHTING MEASURES**

- ❖ No special requirements
- ❖ Flash point over 212°F (100°C)

**SECTION 6. - ACCIDENTAL RELEASE MEASURES**

- ❖ Spillage may be cleaned with water and/or absorbed on sand, cellulose, or vermiculite. Washing should be disposed of in a sanitary sewer as product contains some BOD loading.
- ❖ Secondary containment may be accomplished by diking using the material mentioned above or sorbert pillows and dikes.

**SECTION 7. - HANDLING AND STORAGE**

- ❖ Store in closed containers in cool and dry environment, preferably not to exceed 33°C.
- ❖ High temperature storage accelerates product degradation although product remains non-hazardous.



## **SECTION 8. - EXPOSURE CONTROLS/PERSONAL PROTECTION**

- ❖ No special precautions necessary. Normal hygiene practices.

## **SECTION 9. - PHYSICAL AND CHEMICAL PROPERTIES**

- ❖ Appearance and odor: Blackish brown viscous liquid with burnt sugar odor and taste.
- ❖ Specific Gravity: 1.25-1.40, Boiling Point: 102-107°C.
- ❖ Solubility in water: Complete

## **SECTION 10. - STABILITY AND REACTIVITY**

- ❖ No known hazardous incompatibilities

## **SECTION 11. - TOXICOLOGICAL INFORMATION**

- ❖ No known acute or chronic health hazards

## **SECTION 12. - ECOLOGICAL INFORMATION**

- ❖ May contribute to biochemical oxygen demand (BOD) and chemical oxygen demand (COD).

## **SECTION 13. - DISPOSAL CONSIDERATIONS**

- ❖ Conventional methods consistent with local, state and federal regulations.

## **SECTION 14. - TRANSPORT INFORMATION**

- ❖ Listed under "CAMEL" OR "BURNT SUGAR"
- ❖ NAFTA Harmonized Tariff Classification Code: 1702-90
- ❖ No hazardous or special marking required

## **SECTION 15. - REGULATORY INFORMATION**

- ❖ U.S. Code of Federal Regulations: Title 21 - Food and Drugs Section 73.85 (CAMEL), Section 182.1235 (GRAS).
- ❖ Food Chemicals Codex, "CAMEL".
- ❖ European Directives: 94/36/EC 95/45/EC

## **SECTION 16. - OTHER INFORMATION**

- ❖ The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide.

