

# HAZARD ANALYSIS CRITICAL CONTROL POINT PLAN (HACCP) -LIQUID CARAMEL COLOR SUMMARY

## 1.0 INTRODUCTION

### 1.1 CARAMEL COLOR

- 1.1.1 Caramel Color (Caramel) is defined in Title 21 of the U.S. Code of Federal Regulations, Section 73.85 (21 CFR 73.85) as: "The color additive, caramel, is the dark-brown liquid or solid material resulting from the carefully controlled heat treatment of food grade carbohydrates". This regulation also defines the specific carbohydrates and the acids, alkalis, or salts that may be used to manufacture Caramel.
- 1.1.2 Caramel is GRAS according to 21 CFR 182.1235.
- 1.1.3 The CAS number is: 8028-89-5. The INS number is 150. EINECS is 232-435-9.
- 1.1.4 Sethness Roquette Caramel Color, with the exception of some products made for export or industrial customers, meets the specific requirements as described in the monograph of the Food Chemicals Codex current edition.
- 1.1.5 Sethness Roquette Caramel Colors, with the exception of some specialty products, meet international specifications including JECFA and the European Directive EU No 231/2012.

### 1.2 PREREQUISITES FOR HACCP

Many safety, quality, and sanitation programs are in place at Sethness Products Company (SPC) in addition to the HACCP program. These programs continue to be reviewed and expanded to ensure that Sethness Products Company produces the safest and highest quality Caramel Color possible. These programs include:

- 1.2.1 GMP: 21 CFR 117, and Master Sanitation and Master Maintenance Schedules.
- 1.2.2 Customer Complaint and Retain Sample Programs.
- 1.2.3 Product Recall Programs, including semi-annual traceability tests.
- 1.2.4 Pest Control Program (certified contractor).
- 1.2.5 Chemical Sensitivity Control program especially for sulfite. There are no protein allergens used at Sethness Products Company.
- 1.2.6 Quality Assurance Programs, including lab responsibility and specifications for all incoming, in-process and final products. Every lot of incoming raw material and every lot of final product is analyzed and documented. Audits are conducted monthly by Plant Food Safety Committee and annually by a 3<sup>rd</sup> party.
- 1.2.7 Calibration Program using NIST standards or NIST traceable standards.
- 1.2.8 Glass, brittle plastic, ceramic and wood control program.

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- 1.2.9 Food Defense and Safety Program
- 1.2.10 Crisis Management Program
- 1.2.11 Health and Wellness Policy
- 1.2.12 Quality Review and Audit Procedures

## 2.0 HACCP OVERVIEW

### 2.1 BIOLOGICAL HAZARDS

Sethness Roquette Caramel Colors manufactured by SPC have been used throughout the world for 140 years, and as far as is known, has never been the cause of any foodborne illness or injury.

No pathogenic microorganisms can exist in the raw materials that are used to manufacture Caramel Color due to their acidity or alkalinity (such as 93% sulfuric acid, 30% aqua ammonia, 45% potassium hydroxide and 50% sodium hydroxide). No pathogenic microorganisms can exist in the major liquid carbohydrate raw materials because of their low pH (typically less than 4.5), high solids content (76-85% dry substance), high osmotic pressure and high storage temperatures (above 165°F (73.89°C)).

Further, the caramelization process is in and of itself a sterilization procedure as the reactants are processed at temperatures of not less than 250°F (121.1°C) and not less than 60 minutes. The resulting products contain significant amounts of organic acids and are generally low in pH, while being not less than 50% solids. Many products are 60 to 75% solids and have pH's less than 4.0.

No pathogenic microorganisms have ever been known to be identified in any undiluted Caramel Color. Further routine microbiological profiles of liquid and powder Caramel Colors, which are obtained for "quality" purposes, indicate that both the liquid and powder products are essentially sterile.

Occasionally very minor microbial populations are detected as the commercial products are not handled and packaged as sterile commodities.

### 2.2 CHEMICAL HAZARDS

SPC uses only raw materials that have been processed and refined. SPC has written assurances from carbohydrate suppliers that these materials have been tested and are free of significant residues such as pesticides and herbicides. In addition, chemical raw materials must meet Food Chemicals Codex standards.

Any possibility of excess chemical, such as the reactants ammonia or sulfite salts, are controlled by several quality checks throughout the system as shown on the attached flow diagram.

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### 2.3 PHYSICAL HAZARDS

For liquid Caramel Color, filtration is a better safety measure than the use of metal detection or magnets. Liquid batches are filtered at least twice during processing. The principle filter is a bag filter with a 5 micron pore size or a 250 micron stainless steel screen. Final filters all have openings no larger than 840 microns (20 mesh). Filters are most often 400 microns (37 mesh), or less. The 5000 micron CCP is 2000 microns less than the FDA 7,000 micron minimum stated level.

### 3.0 HACCP PLAN

Sethness Products Company has been using HACCP plans for many years. The HACCP plans have been reviewed yearly and comply with the requirements of AIBI-CS, and BRC (Global Standard for Food Safety). The complete plan includes: plant information, prerequisites, regulations, complete flow diagrams, raw material hazard analysis, process step hazard analysis, Master plans, validations, deviation reports, revision history and training.

Our HACCP Plans are "Certified" as they are included in the BRC Certification against the international standards of the Global Food Safety Initiative.

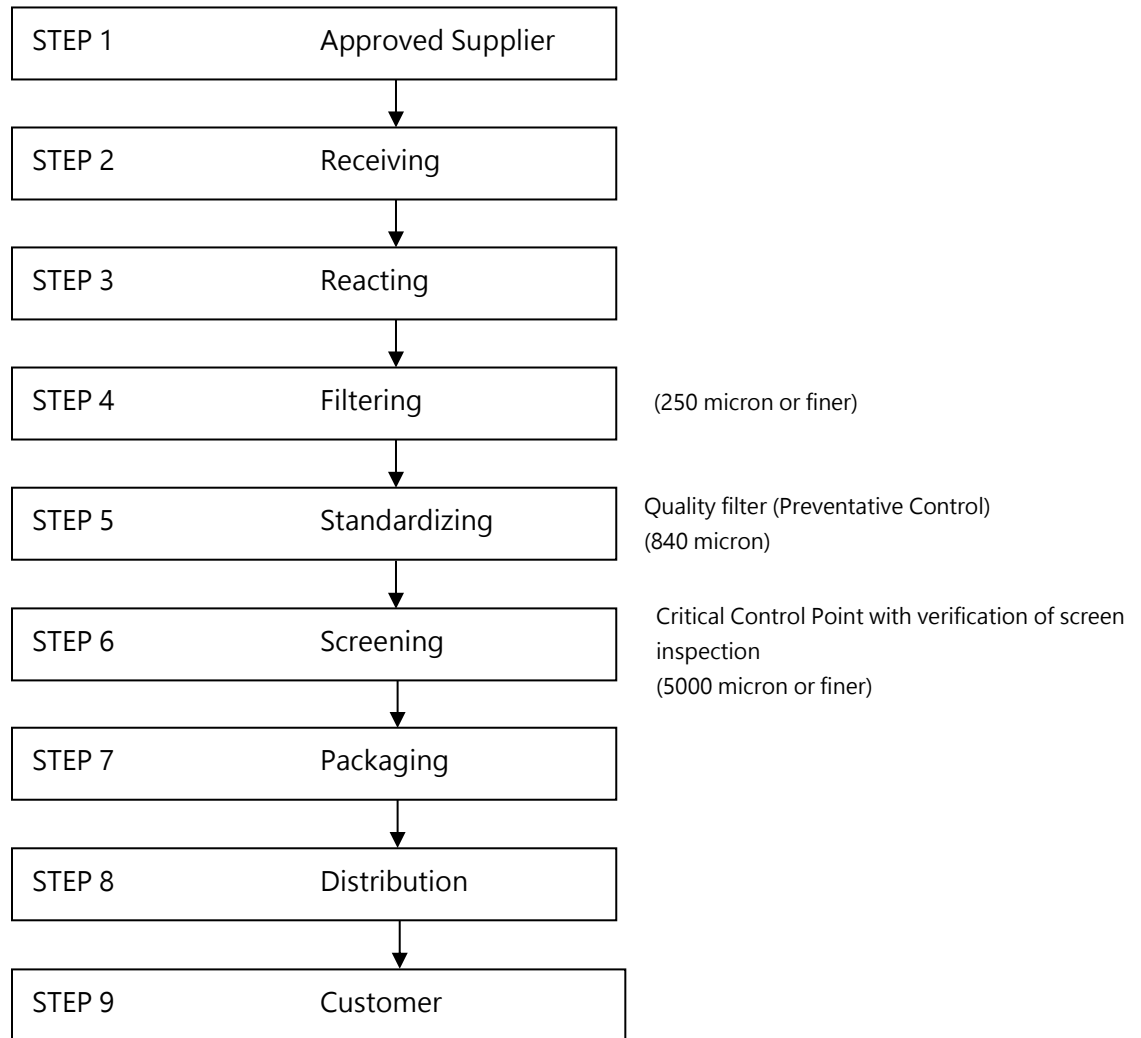
Please find attached the simplified flow diagram.

### 4.0 ACRONYMS

4.1	CFR	Code of Federal Regulation
4.2	HACCP	Hazard Analysis Critical Control Point
4.3	CCP	Critical Control Point
4.4	CAS	Chemical Abstract Services
4.5	INS	International Numbering System for food additives
4.6	FCC	Food Chemical Codex
4.7	FAO	Food and Agriculture Organization of the United Nations
4.8	WHO	World Health Organization of the United Nations
4.9	JECFA	Joint FAO/WHO Expert Committee on Food Additives
4.10	GMP	Good Manufacturing Practice
4.11	EINECS	European Inventory of Existing Commercial Chemical Substances
4.12	AIBI-CS	American Institute of Baking International-Certification Services
4.13	BRC	British Retail Consortium
4.14	GRAS	Generally Recognized as Safe
4.15	FDA	U.S. Food and Drug Association

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## LIQUID CARAMEL COLOR HACCP PLAN FLOW CHART



Control Points in case of hazards located at steps:

Physical: 1, 2, 3, 4, 5, 6, 7, and final product analysis

Chemical: 1, 2, 3, 5, and final product analysis

Biological: 1, 2, 3, and final product analysis

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