HAZARD ANALYSIS CRITICAL CONTROL POINT PLAN (HACCP) - POWDER 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 3rd party.

1.2.7 Calibration Program using NIST standards or NIST traceable standards.

1.2.8 Glass, brittle plastic, ceramic and wood control program.
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.

Powder Caramel Colors are manufactured by spray drying feedstocks of Liquid Caramel Colors. These feedstocks are held at temperatures about 140°F (60°C) for times in excess of those needed for pasteurization prior to drying. The high temperature is a prerequisite to the drying of liquid into a powder. The powder is not susceptible to microbial growth as the moisture content is typically less than 4%.

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 for pH adjustment is controlled by several quality checks throughout the system as shown on the attached flow diagram.
2.3 PHYSICAL HAZARDS
For Powder Caramel Color, the manufactured, filtered, and standardized Liquid Caramel Color is analyzed for color, pH and specific gravity before drying. This liquid must pass through an atomizer. Finally, dried powder must pass through a final 840 micron screen and metal detector before being packaged. The metal detector is designed to detect ferrous metal at 0.9 mm, non-ferrous at 1.0 mm and stainless steel at 1.4 mm. The CCP for Powder Caramel Color has been set at 2.8 mm (ss). In addition, samples of the powdered product are taken every two hours and the composite tested for ability to pass through a 100 mesh (149 micron) screen.

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
POWDER 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