February 5, 2017

RE: HACCP COMPLIANCE

Niacet Corporation guarantees that all food chemical products (FCC grades) manufactured at our Niagara Falls, NY facility are produced under a HACCP program to prevent all products from being adulterated with microbiological, chemical, or physical contaminants that could cause injury or illness to the user.

The HACCP program monitors critical control limits at specified points in the process to verify that all products are manufactured under controlled conditions so that product safety is assured. Written preventative actions are in place to prevent adulterated product from reaching the user and all monitoring documents are audited to verify that all products are within specification prior to shipment.

Sincerely,

NIACET CORPORATION

Salvatore J. D'Angelo

Salvatore J. D'Angelo
Manager, Quality Assurance &
Regulatory Affairs

400 47TH STREET, NIAGARA FALLS, NY 14304 · (716) 285-1474 · (800) 828-1207 · FAX (716) 285-1497
WWW.NIACET.COM

NIACET CORPORATION 1/04/15
MASTER FILE (HACCP)
CALCIUM PROPIONATE

FDA Bio Number 19691631666 ISO 9001/2008 BVQI Registration Number 191514

A. Address

a. Administrative
Niacet Corporation
400 47th Street
Niagara Falls, NY 14304

b. Manufacturing Facility
Niacet Corporation
400 47th Street
Niagara Falls, NY 14304

B. Responsible Official
Salvatore J. D'Angelo
Manager, Quality Assurance & Regulatory Affairs
Niacet Corporation
400 47th Street
Niagara Falls, NY 14304

C. Statement of Commitment

Calcium Propionate as supplied by Niacet Corporation will be manufactured in accordance with methods described in this document. The HACCP limits are managed by adherence to raw material, and final product specifications.

D. Organization and Personnel

Organizational Chart Attached

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E. Buildings and Facilities

The operations for production of Calcium Propionate are carried out in industrial steel supported buildings. The buildings are equipped with all utilities including 440v electricity, potable water, natural gas, and sewers. All operations occur within industrial process equipment. Storage facilities for in-process, and finished products are also within industrial buildings. Niacet utilizes pest control contractors licensed by New York state for all its operations.

F. Equipment Design and Location – Operating Instructions Attached

1. Propionic Acid storage tank, stainless steel. Fully enclosed and vented.
2. Calcium Oxide storage tank, stainless steel. Fully enclosed and vented.
3. Reactor with vertical agitator, stainless steel, fully enclosed and vented.
4. Filters- Pre coat Rotary.
5. Feed tanks fully enclosed, stainless steel.
6. Spray dryer, atomizer type, or Centrifuge and Fluid bed dryer
7. Sieving, Bulk bin, finished product storage, fully enclosed, stainless steel bin.
8. Bag Packer, stainless steel. Weigh Scale
9. Metal Detector , Check Weigher, Palletizer, Store
10. All equipment is fully enclosed and interconnected through stainless steel piping for liquids or stainless steel ducting for powder and air.

G. Article- Components and Composition

a. Calcium Propionate FCC

Calcium Propionate is FDA GRAS approved for use as a chemical food additive. The intended market for this product is primarily commercial bakeries. It is a minor ingredient added to flour as an antimicrobial agent. It is further processed prior to consumption. It is regulated under CFR 21 Part 184.1221. It is antimicrobial by nature and not subject to attack. It is produced entirely in fully enclosed equipment suitable for food chemical additive manufacture. The hazards associated with production of this product are managed by inspection of all finished goods for FCC specification requirements. Production is accomplished according to detailed operating instructions. Testing is conducted in accordance with Food Chemicals Codex test methods.

Calcium Propionate and water are the reaction products of a neutralization of Propionic Acid (CH_3CH_2COOH) and Calcium Hydroxide $Ca(OH_2)$.The exothermic reaction is carried out in a cooled vessel using metered amounts of reactants. The resulting solution of Calcium Propionate is filtered through a diatomaceous earth rotary filter to a feed tank. The filtered solution is fed to a drying unit to remove moisture. The dried material is fed to a storage bin, and packaged for distribution. Cleaning validation is based on observation of physical equipment and other means. Water is supplied to Niacet via the Niagara Falls Water Board through municipal lines. Water is tested for pathogens once/year min. Specifications for raw materials used in manufacturing Calcium Propionate are certified by suppliers. Acceptance is via QA department review of the COA as follows:

Propionic Acid	
Assay (wt%) (minimum)	99.5
Appearance	Clear and water white
Color Pt Co. (maximum)	10
Specific Gravity @ 20C	0.993-0.997
Water Content (wt%) (maximum)	0.25
Aldehyde (wt%) (maximum)	0.05
Heavy Metals as Pb, ppm (maximum)	0.5

Calcium Oxide	
CaO (wt%) (available minimum)	94
Sodium Chloride, NaCl (wt%) (maximum)	0.01
Heavy Metals (as Pb) (ppm) (maximum)	2

The Specifications for the finished Calcium Propionate are as follows:

Purity (Dry Basis)	99.0% Minimum (as Calcium Propionate)
Water (wt.%) (maximum)	5.0
pH of 10% Aqueous Solution	7.5 – 9.0
Insolubles% (maximum)	0.2
Fluoride ppm (maximum)	30
Magnesium % (maximium)	0.4
Arsenic as (As), ppm (maximum)	3
Lead (ppm) (maximum)	2
Appearance	White Powder/Granules/Crystals

b. Packaging and Labeling

The finished Calcium Propionate is packaged in 50 lb, or 25 kg kraft paper bags containing integral poly liner. The bags are sealed closed. These packages cannot be opened without destruction of the paper bag material. Product labels are numbered consecutively by pallet with a record kept with the production manager. Bulk Sacks may be packaged on request.

H. Production and Process Controls

a. In Process Sampling Procedure:

A 4 oz min. sample is obtained for laboratory analysis from each consecutive pallet, or sack. Laboratory tests for pH and moisture are recorded for progressive samples. Samples are consolidated into a composite sample for final product approval tests prior to release. A lot size is approximately 80,000 lbs.

b. Reprocessing:

Any material not meeting all of the specification requirements is rejected. This material may be reprocessed and tested to FCC specifications.

c. Packaging and Labeling:

All packages are identified with full product and grade nomenclature and weight. Lots and package number are identified by the last digits of year followed by the Julian calendar date (1-365), followed by drum, or pallet number. Any rejected product is marked as such and segregated from product approved for distribution. Laboratory maintains records of all rejected material.

d. Stability and Expiration Dating:

The shelf life of Calcium Propionate is generally considered to be indefinite, however, a product retest is recommended after two years to ensure conformance to specification. This information is based on past experience including historical data.

e. Product Retrieval Policy

Niacet Corporations retrieval policy addresses the retrieval of material from the Transportation and distribution network and from customers initiated by Niacet Corporation. The decision to retrieve material may be caused by Niacet Corporation's concern over the safety or performance of the product or in response to regulatory action. If a retrieval is in response to a regulatory requirement, it is a recall and the specific requirements of the applicable regulation must be fulfilled. The Manager of Quality Assurance and Regulatory Affairs shall be responsible for initiating the retrieval procedures should they be necessary.

The Customer Service Department shall maintain complete records covering The transportation and distribution of material which may be subject to retrieval, Niacet Corporation shall maintain a system which will permit determination of the amount, date and destination of all material within a lot or series of lots. It shall be the responsibility of the distributor to keep records adequate to permit customers of materials from any lots distributed, together with amounts and dates of shipments to be identified. The Customer Service Department shall conduct a mock recall twice per year minimum, and present the results to the Manager, Quality Assurance & Regulatory Affairs. Percent accounted for and time for recall will be recorded.

f. Revalidation

Niacet maintains a quality assurance system in place which requires revalidation whenever there are changes in raw material suppliers, formulation, equipment, or processes which could impact on product characteristics, or effectiveness, and whenever there are changes in product characteristics. This revalidation is managed through Niacet's product change control procedure.

The HACCP Seven Principles

Principle1. Conduct a hazard analysis. Niacet determines the food safety hazards and identify the preventative measures the plant can apply to control these hazards. A food safety hazard can be a biological, chemical, or physical property that may cause a food chemical additive to be unsafe for consumption.

Principle 2. Identify Control Points and Critical Control Points. Control points and Critical Control Points are a point, step, or procedure in a process at which control may be applied and as a result, a hazard may be prevented, eliminated, or reduced to an acceptable level.

Principle 3. Establish Control limits Critical limits for each critical control point. A critical limit is the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level.

Principle 4. Establish monitoring requirements. Monitoring activities are necessary to ensure that the process is under control at each control point and critical control point.

Principal 5. Establish Corrective Actions. These are actions to be taken when monitoring indicates a deviation from an established critical limit. This requires Niacet's HACCP plan to identify the corrective actions to be taken if a critical limit is not met. Corrective actions are intended to ensure that no product injurious to health or otherwise adulterated as a result of the deviation enters commerce.

Principal 6. Establish Recordkeeping Procedures. The HACCP regulation requires that all of the required documents are maintained. These include the HACCP plan, and records documenting the monitoring of critical control points, critical limits, verification activities, and the handling of processing deviations.

Principal 7. Establish a procedure to ensure the HACCP system is working as intended. Validation ensures that the production units are designed to do what they were designed to do. In essence producing on specification products that are free from hazards. Verification procedures may include such activities such as review of HACCP plans, CP records, control limits, critical limits, and analytical data.

PREREQUISITE PROGRAMS

Following is a list of Prerequisite programs that Niacet employs in our manufacturing process. These programs are contained in the context of our Best Management Practices Plan (BMPP), ISO 9001/2000 Quality Manual, or other supporting documents. In some cases a prerequisite program may be mandated by a regulatory agency.

Premises

a) Buildings and Utilities
b) Infrastructure
c) Environmental Permits

Receiving/Storage

a) Raw Material Management
b) Receiving Storage/ Distribution
c) Certificate of Analysis
d) Letters of Guarantee
e) Hold and Release
f) Truck/Railcar/Carrier Inspection
g) Label review for accuracy
proper Product/Lot No/ wt.
h) Shipping

General Quality Systems / Monitoring Programs/GMPs

a) Use of approved Chemicals
b) Use of approved suppliers
c) Rework Practices
d) Operating Procedures
e) Extraneous Detection
f) Control of Documents
g) Control of Records

Personnel Training Program

a) Employee Hygiene/ Employee Practices
b) Unit specific training
c) Environmental/Security Training
e) OSHA/DOT/GMP Training
f) HACCP Training

Health & Safety Recalls

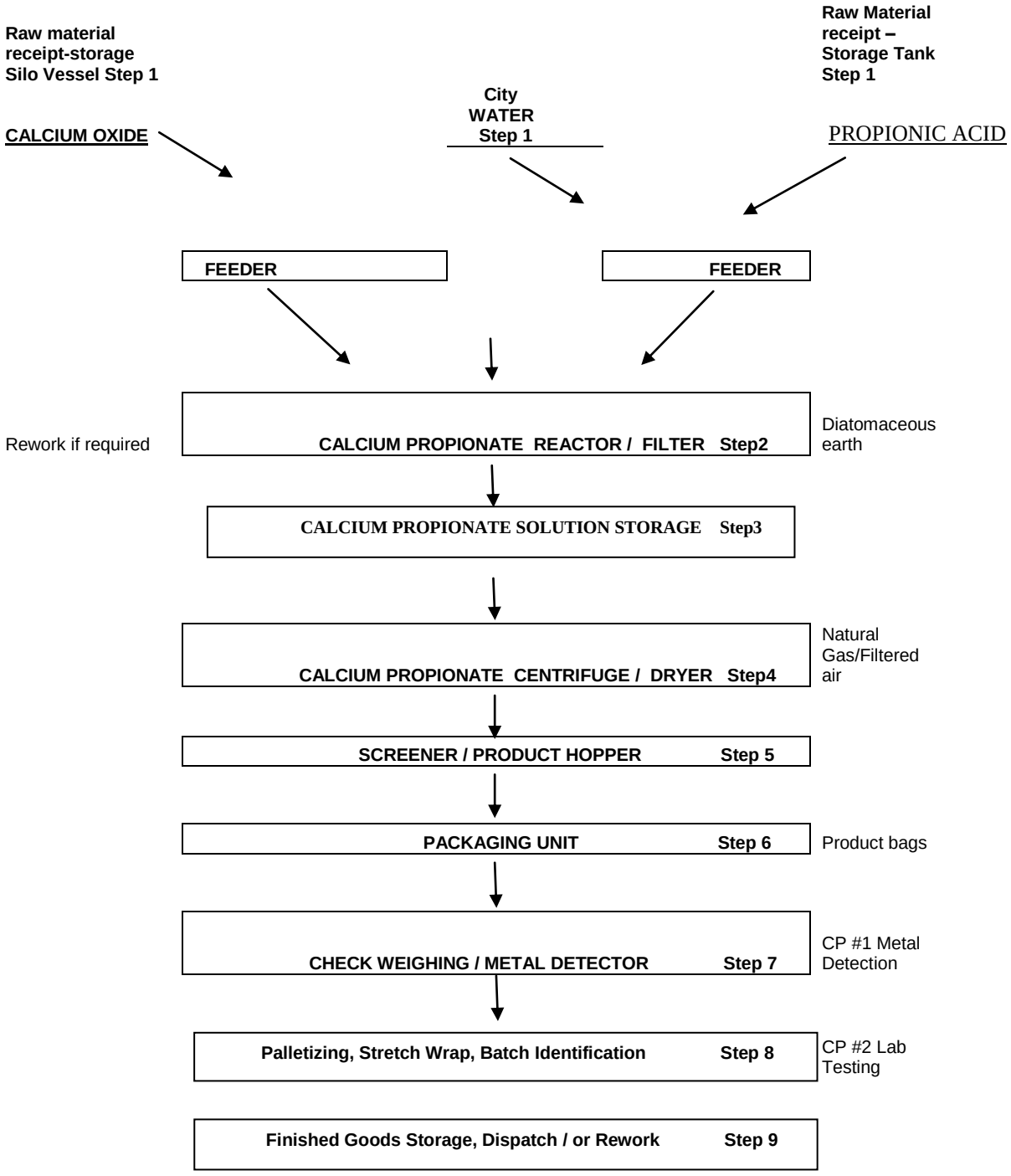
a) Hold & Release
b) Recall Procedures
c) Traceability/ Lot Coding

Equipment Performance and Maintenance

a) Preventative Maintenance
b)Equipment Calibration
c) Compressed Air Filtration
d) Equipment Design

Sanitation

a) Pest Control
b) Equipment Cleaning
c) Housekeeping
d) Equipment Inspection



As a producer: These are our controls within the HACCP framework:

Calcium Propionate is Antimicrobial by nature and not subject to attack

PHYSICAL HAZARDS :

Materials of Construction/ Visual Inspection / Sifting of Product / Sealing of Product / Metal Detection CP1

CHEMICAL HAZARDS:

Raw Material control /Process Intermediate control/ Weight and Volume Control/ Finished Goods Control CP2

HAZARD ANALYSIS AND RISK ASSESSMENT STATEMENT

Niacet Corporation metal organic acid salt products including Calcium Propionate are anti microbial compounds not subject to attack. They are produced from synthetic raw materials that are received via bulk railcar or tank truck. Niacet Corporation has no allergens in the process, or on site.

Hazard Analysis concludes health risks may be attributed to contamination from tramp metal associated with stainless steel production equipment. The risk of injury due to metal in the product is considered to be low due to the minor amount used and reprocessing by the end user.. Food Chemicals Codex (FCC) guidelines also require Calcium Propionate FCC to meet specification. The risk of injury due to off spec product is considered to be low due to the minor amount consumed, typically 3-5 oz per 100 lbs of flour. Our Control points include metal detection of each bag of finished product, and specification testing of each lot. Neither of these control points is considered to be critical due to the minor ingredient use of this product.

HAZARD ANALYSIS

Process Step	Food Safety Hazard	Reasonably Likely to Occur ?	Basis	If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level ?	CP
City Water	Biological	No	Municipal records		
	Chemical	No	Municipal records		
	Physical	None			
Calcium Oxide	Biological	None			
	Chemical	No	Certificates of Analysis		
	Physical	None			
Propionic Acid	Biological	None			
	Chemical	No	Certificates of Analysis		
	Physical	None			
Reaction	Biological	None			
	Chemical	No	In Process Testing		
	Physical	No	All enclosed system		
Dryers	Biological	None			
	Chemical	None			
	Physical	No	All enclosed system		
Hopper	Biological	None			
	Chemical	None			
	Physical	No	All enclosed system		
Packaging Materials	Biological	None	FCC Grade poly lined		
	Chemical	None	Kraft Paper Bags/Sacks		
	Physical	None			
Packaging System	Biological	None			
	Chemical	None			
	Physical	low	Tramp metal from Equipment	Metal Detection	CP 1
Packaged	Biological	None			
	Chemical	yes	May be off Spec	Meet FCC Specs	CP 2
	Physical	No	Bags are Sealed		
Shipping	Biological	None			
	Chemical	None	Certificates of analysis		
	Physical	No	Bags are Sealed		

Control Point (CP) #1 Documentation- Metal Detection

Purpose: To define food chemical safety limits and monitoring and corrective action requirements.

Control Point ID	Metal Detection
Process Step	Packaged Goods
Hazard	Metal Fragment in Product
Limits	3.0 mm Stainless, 3.5 mm non ferrous 2.5mm Ferrous Test Coupons
Monitoring Activity & Frequency	Test all filled bags prior to palletizing Run Test Coupon min 1/shift. If test piece fails, repair unit or determine cause of failure. Place all product on hold since the last acceptable check. Re check all bags prior to the failure. Log Sheets must be signed by the Operator, and approved by the Production Manager, or Designee.
Corrective Action Activity	Reject Bag(s) and Investigate Cause of non-conformance
Responsibility for Monitoring & Corrective Action	Production Manager or Designee
Records & Location	Manufacturing Log Sheet –
Minimum CP Verification	Production Engineer or designee will witness the monitoring activity at least once per day or by other means.

Control Point (CP) #2 Documentation- FCC Tests

Purpose: To define food chemical safety limits and monitoring and corrective action requirements.

Control Point ID	Finished Product FCC Tests
Process Step	Packaged Goods
Hazard	Out of FCC Specification
Control Limits	Product Specifications
Monitoring Activity & Frequency	Test all Parameters on each Lot.
Corrective Action Activity	Reject Lot and Investigate Cause of non-conformance
Responsibility for Monitoring & Corrective Action	Quality Assurance Manager or Designee
Records & Location	Finished Product log & Reject Log (QA Lab File)
Minimum CP Verification	Review Analytical Data for each lot prior to release. Log books must be signed by the QA analyst, and approved by the QA Manager, or Designee

Approved,

Team Leader Salvatore D'Angelo 1/15
Production Scott Barnum
Engineering Mark Przybylski
Supervisors
Calcium Propionate Operators