

Sodium Acetate/ Diacetate HACCP



NIACET CORPORATION
MASTER FILE (HACCP)
SODIUM ACETATE/DIACETATE

01/05/15

FDA Bio Number 19691631666

ISO 9001/2000 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

Sodium Acetate/Diacetate 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 acceptance, and final product specifications.

D. Organization and Personnel

Organizational Chart Attached

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

E. Buildings and Facilities

The operations for production of Sodium Acetate/Diacetate 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. Acetic Acid storage tank, stainless steel. Fully enclosed and vented.
2. Sodium Carbonate storage tank, stainless steel. Fully enclosed and vented.
3. Reactor with vertical agitator, stainless steel, fully enclosed and vented.
4. Sodium Acetate/Diacetate mills.
5. Feed machinery fully enclosed, stainless steel.
6. Product dryers, stainless steel, filtered drying air
7. Bulk bin, finished product storage, fully enclosed, stainless steel bin.
8. Sieves/Magnets
9. Bag Packer, stainless steel. Weigh Scale
10. Palletize/ Stretch Wrap, Store

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. Sodium Acetate/Diacetate FCC

Sodium Acetate/Diacetate are FDA GRAS approved for use as chemical food additives. They are antimicrobial by nature and not subject to attack. They are minor ingredients added to flour or spice blends and further processed prior to consumption. They are produced entirely in fully enclosed equipment suitable for food chemical additive manufacture. The hazards associated with production of these products are managed by inspection of all finished goods for FCC specification requirements. Production is

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accomplished according to detailed operating instructions. Testing is conducted in accordance with Food Chemicals Codex test methods.

Sodium Acetate/Diacetate and water are the reaction products of a neutralization of Acetic Acid (CH_3COOH) and Sodium Carbonate (Na_2CO_3). The exothermic reaction is carried out in a reactor using metered amounts of reactants the reactor is heated by non contact steam heat.. Choice of product made is controlled by altering the ratio of reactants in the reactor. The resulting formation of Sodium Acetate or Diacetate powder and water are fed to a product dryer to remove excess moisture. The dryers are heated with natural gas/ filtered air and non contact steam. 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 Sodium Acetate/Diacetate are certified by suppliers. Acceptance is via QA department review of the COA as follows:

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Acetic 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

Sodium Carbonate

Na_2CO_3 (wt%)	99-100%
Sodium Chloride, NaCl (wt%)(maximum)	0.01
Iron, Fe ppm (maximum)	7
Water insolubles (wt%)(maximum)	0.2

Specifications for the finished Sodium Acetate are as follows:

Purity (Dry Basis)	99% - 101 % by weight, (as Sodium Acetate)
Loss on Drying (wt.%) (max)	1.0
Water (wt.%) (max)	1.0
pH of 10% Aqueous Solution	7.5 – 9.2
Halides (wt%) (max as NaCl)	0.1
Alkalinity	NMT 0.2% (as NaOH)
Potassium Compounds	Passes Test
Iron (as Fe) ppm (max)	10
Arsenic as (As), ppm (max)	3

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Sulfate ppm) (max)	25
Lead (ppm) (max)	2
Appearance	Fine White Crystals

Specifications for the finished Sodium Diacetate are as follows:

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Purity (Dry Basis)	58.0% to 60%
	(as Sodium Acetate)
Acetic Acid	39.0% to 41.0%
Water (wt.%(max)	2%
pH of 10 % solution (typ)	4.5-5.0
Oxidizable Impurities (wt.%(max)	0.1% (as Formic Acid)
Lead ppm (max)	2
Iron (as Fe) ppm (max)	10
Granulation (through 100 mesh)	>90% Typical
Appearance	White Powder

b. Packaging and Labeling

The finished Sodium Acetate/Diacetate 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.

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 10th drum. Laboratory tests for pH, or acid content and moisture are recorded for each. Samples are consolidated into a composite sample for final product approval tests prior to release. A lot size is up to 80,000 lbs.

b. Reprocessing:

Any material not meeting all of the specification requirements is rejected. This material may be reprocessed under direction of the Production Engineer.

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 digit 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 Sodium Acetate 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.

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

Principle 1. 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 Critical Control Points. A critical control point is 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 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 Critical Control Point monitoring requirements. Monitoring activities are necessary to ensure that the process is under control at each critical control point.

Principle 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.

Principle 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.

Principle 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, CCP records, 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),

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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.

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

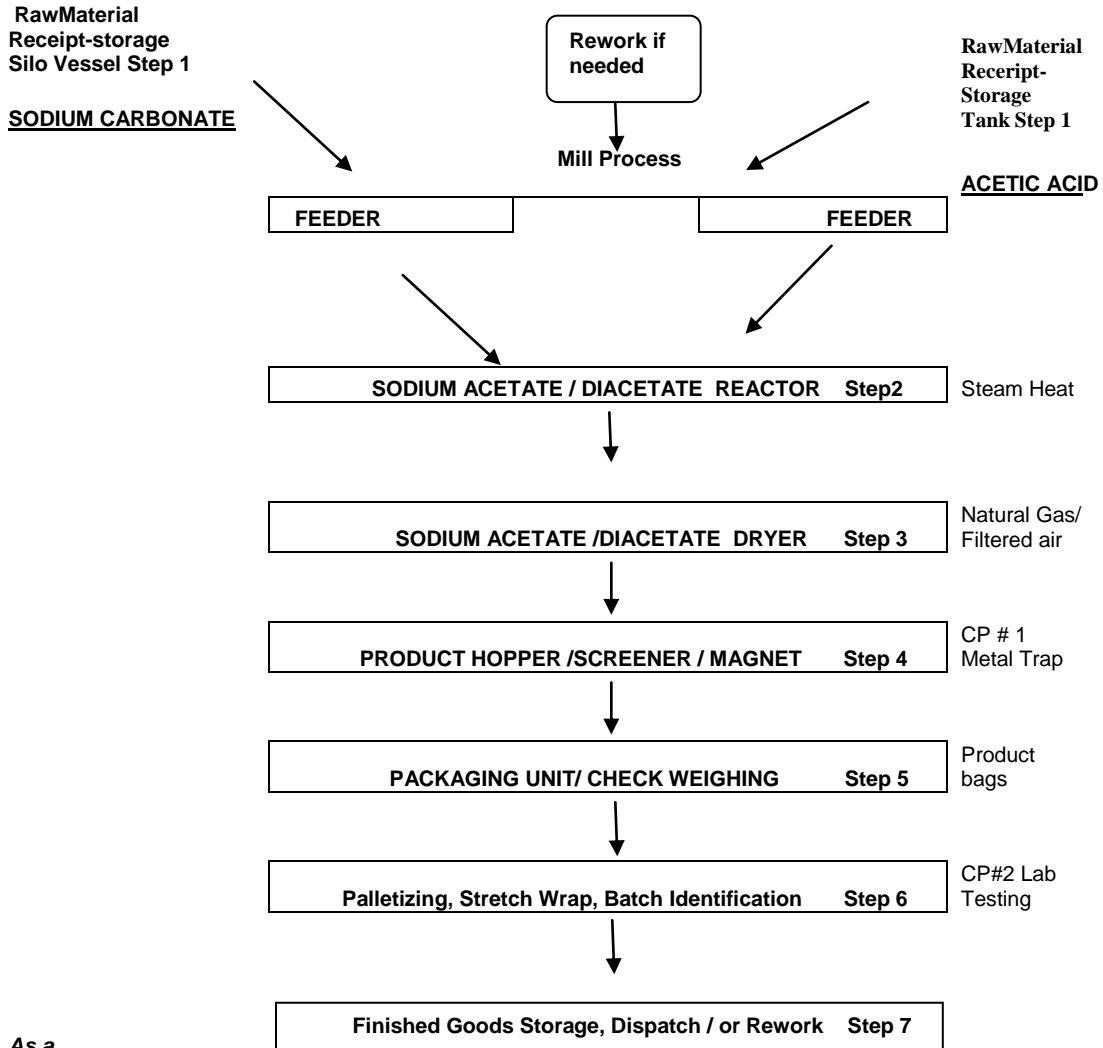
Equipment Performance and Maintenance

- 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

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

Sodium Acetate/Diacetate is Antimicrobial by nature and not subject to attack

PHYSICAL HAZARDS

Materials of Construction/ Visual Inspection / Sifting of Product / Sealing of Product / Magnets

CHEMICAL HAZARDS:

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

HAZARD ANALYSIS AND RISK ASSESSMENT STATEMENT

Niacet Corporation metal organic acid salt products including Sodium Acetate/Diacetate are anti microbial compounds not subject to attack. They are produced from synthetic raw materials that are received via bulk railcar or tank truck. Sodium Acetate/Diacetate contains no natural ingredients. 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. Food Chemicals Codex (FCC) guidelines also require Sodium Acetate/Diacetate FCC to meet specification. The risk of injury due to off spec product is considered to be low. Our control points includes periodic inspection of sieves and magnets along with specification testing of each lot. These control points are not considered to be critical due to the minor ingredient use of these products.

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HAZARD ANALYSIS

<u>Process Step</u>	<u>Food Safety Hazard</u>	<u>Reasonably Likely to Occur ?</u>	<u>Basis</u>	<u>If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level ?</u>	<u>CP</u>
City Water	Biological Chemical Physical	No No None	Municipal records Municipal records		
Soda Ash	Biological Chemical Physical	None No None	Certificates of Analysis		
Acetic Acid	Biological Chemical Physical	None No None	Certificates of Analysis		
Reaction	Biological Chemical Physical	None No No	In Process Testing All enclosed system		
Dryer	Biological Chemical Physical	None None No	All enclosed system		
Hopper	Biological Chemical Physical	None None No	All enclosed system		
Packaging Materials	Biological Chemical Physical	None None None	FCC Grade poly lined Kraft Paper Bags		
Packaging System	Biological Chemical Physical	None None low	Tramp material from Equipment		
Packaged	Biological Chemical Physical	None yes No	May be off Spec Bags are Sealed	Meet FCC Specs #7	

Control Point (CP) #1 Sieves and Magnets

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

<u>Control Point ID</u>	<u>Metal/Foreign Material Detection</u>
Process Step	In Process
Hazard	Unusual Metal/Foreign Material
Control Limits	Metal Buildup/ Foreign material
Monitoring Activity & Frequency	Check each shift
Corrective Action Activity	Reject prior shift product and Investigate Cause of non-conformance
Responsibility for Monitoring & Corrective Action	Production Manager or Designee
Records & Location	Production Log (Production Engineer Office)
Minimum CP Verification	Review Operator log sheets for each lot prior to release. Log sheets must be initialed by the Operator and reviewed by the Production Manager or Designee.

Control Point (CP) #2 Documentation- FCC Tests

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

<u>Control Point ID</u>	<u>Finished Product FCC Tests</u>
Process Step	Packaged Goods
Hazard	Out of FCC specification
Control Limits	Product Specifications
Monitoring Activity & Frequency	Check each lot
Corrective Action Activity	Reject product and Investigate Cause of non-conformance
Responsibility for Monitoring & Corrective Action	Quality Assurance Manager or Designee
Records & Location	Finished product Log and 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 reviewed by the QA Manager or Designee.

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S.J. D'Angelo Approved 1/15
Production Scott Barnum
Engineering Dave Van Kerkhove
Supervisors
Sodium Acetate Operators