

4.0 - GOOD MANUFACTURING PRACTICES

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**4.1 INTRODUCTION:**

*The following information provides the essence of what Good Manufacturing Practices (GMP) are all about; i.e., conducting manufacturing operations in such a manner that protects all products produced from contamination or from the potential of becoming contaminated.*

*To meet these principles, it will take the interest, cooperation, and alertness of all employees. Operators, shippers, maintenance personnel, managers, and staff must work together to assure that GMP requirements are met.*

**4.2 OPERATING PROCEDURES:**

*Each production unit shall maintain standard operating procedures (SOP's). Operators shall be familiar with these instructions and observe the requirements thereof. These procedures should include specific reaction details (e.g. quantities, control parameters, etc.), operating instructions of major equipment/systems, process flow diagrams, raw material handling instructions, and product specifications. Revisions should be issued periodically reflecting any changes or improvements in the daily operating procedures.*

**4.3 SAFETY POLICIES AND PROCEDURES:**

*Specific safety policies and procedures shall be maintained to ensure the safe conduct of all employees. Each individual has an obligation to comply with these policies and procedures to provide the maximum, reasonable level of safety and health within the plant.*

*Appendix 4.0 contains plant safety requirements, policies and procedures.*

**4.4 PROCESS AND CONTROLS:**

*All operations should comply with adequate operating practices to guard against product contamination.*

*Appropriate quality control measures shall be employed to determine that raw materials and products are suitable for their intended usage.*

*Raw materials, other ingredients and rework material should be properly labeled and held in vessels (with lids) suitable to protect against contamination.*

*All equipment used to handle, process or hold raw materials, work-in-process, or finished products should be constructed in such a manner that protects against contamination.*

*Contaminated product or raw materials shall be disposed of in a manner that does not affect other materials.*

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**4.5 CLEANING OPERATIONS:**

*Plant facilities should be maintained in a good condition to prevent product contamination.*

*Cleaning substances used should be free of contamination, safe for use, and adequate to do the job. Effective measures to guard against product contamination by pests should be taken.*

*Product-contact surfaces and work implements should be cleansed as necessary to prevent product contamination.*

**4.6 PEST CONTROL:**

*The pest control program shall be administered by the Regulatory Department. A pest control contractor licensed by the State of New York shall perform the pest control duties. The contractor shall use Catchalls, Glue Boards, and Exterior Bait stations to control pests. The contractor shall report his findings to the Production Coordinator on a monthly basis. The Regulatory Department will use this information to assess the pest control status.*

**4.7 WAREHOUSING AND DISTRIBUTION:**

*Storage and transportation of finished products should be done under conditions that protect product from physical, chemical, or pest contamination.*

*Approved products should be properly identified and stored away from rework or contaminated material (also properly labeled).*

**4.8 GLASS & BRITTLE PLASTIC**

*Niacet Corporation maintains a Glass and Brittle Plastics Policy that is consistent with Good Manufacturing Practices. The purpose of the program is to control any risks that are associated with the use of glass and brittle plastics that cannot be effectively protected or replaced with alternative materials, and are therefore required in the plant environment. Such items may include thermometers, site glass, windows, signal lights, glassware used for chemical tests, etc.*

*Niacet's policy includes the following elements:*

- *Identification of glass and brittle plastic materials in the plant.*
- *Elimination or adequate protection of materials.*
- *Inventory and inspection of materials that cannot be protected.*
- *Action plan to handle any breakage that may occur*
- *Prevention of employees or contractors bringing materials into our facility*
- *Universal authority for reporting glass/brittle plastic breakage incidents.*
- *Defined authority for managing the program*
- *Audit and review of the program for effectiveness during Unit meetings.*

**4.9 CLOTHING & JEWELRY POLICY**

- 1.) *Safety shoes with steel toe or equivalent protection must be worn while working in the plant.*
- 2.) *Hard hat, Safety glasses with side shields, Hearing protection, Respiratory protection, and any other applicable PPE must be worn in designated areas or when performing designated activities. Safety glasses with dark or tinted lenses are not permitted indoors or in low light conditions.*
- 3.) *Facial hair (such as a beard), and long side burns are not permitted on employees who work in the plant where such conditions interfere with proper fit of a respirator face piece, or presents a food safety concern, Long hair must be maintained in a safe manner to avoid an entanglement hazard, or presents a food safety concern.*
- 4.) *Protective clothing issued by Niacet shall be worn at work and must be changed regularly. Clean uniforms must be kept separate from street clothes. Protective clothing such as uniforms must not be worn off site and kept in good condition. Soiled clothing and hard hats, loose clothing, shorts, sleeveless shirts, ripped or torn clothing is prohibited.*
- 5.) *Jewelry with the exception of wristwatches and rings without stones are not permitted in production areas.*
- 6.) *It is prohibited to carry writing implements behind the ear or anywhere else where they may fall.*

**BUREAU VERITAS**  
Certification



## NIACET CORPORATION

400 47TH STREET  
NIAGARA FALLS, NY, 14304

*Bureau Veritas Certification Holding SAS – UK Branch certifies that the Management System of the above organization has been audited and found to be in accordance with the requirements of the Management System standards detailed below.*

**STANDARDS**

## ISO 9001:2008

*Scope of certification*

### MANUFACTURE OF CHEMICALS

Certification cycle start date: **2 August 2015**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **1 August 2018**

Original certification date: **3 August 2012**

Certificate no.: **US007983-1**

**Signed on behalf of BVCH SAS - UK Branch**

Certification body address: 66 Prescott Street, London, E1 8HG, United Kingdom  
Local Office: 390 Benmar Drive, Houston, Texas, USA



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Further clarifications regarding the scope of this certificate and the applicability of the Management System requirements may be obtained by consulting the organization. To check this certificate validity, please call + (800) 937-9311.



March 25, 2015

Niacet Corp.  
400 47<sup>th</sup> street  
Niagara Falls, NY, USA  
14304

Attn: Scott Barnum

Subject: LETTER OF NON-OBJECTION

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We, Gelpac Rouville Packaging Solution registered with the CFIA under the number E235 certifies that all bags manufactured for Niacet Corp. are of Canada/USA origin and produced using raw materials that are safe and approved for product use in contact with food for human consumption as per FDA Regulations.

The paper used is compliant to FDA as per 21 CFR 176.170 and 176.180. The polyethylene film is compliant to FDA as per 21 CFR 177.1520.

Gelpac Rouville Packaging Solution guarantee extends to all bags already delivered, bags in process and all future shipment of bags.



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