



4410 SOUTH 102<sup>ND</sup> STREET

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## SITE QUALITY OVERVIEW DATASHEET FOR DIETARY INGREDIENTS

### Section 1. SITE OVERVIEW

NAME AND ADDRESS OF SITE RESPONSIBLE:	American Laboratories, Inc. Corporate Office: Building 10: 4410 S. 102 <sup>nd</sup> Street Omaha, NE 68127 Building 20: 5020 S. 33 <sup>rd</sup> Street Omaha, NE 68107 Shipping Location: Building 36: 5036 S. 33 <sup>rd</sup> Street Omaha, NE 68107		
SIZE:	“Building 10” – 25,000 sq. ft. “Building 20” – 45,000 sq. ft. “Building 36” – 65,000 sq. ft.	YEAR BUILT:	“Building 10” – 1967 “Building 20” – 1950 “Building 36” – 2000
GENERAL AND PRODUCT LIABILITY INSURANCE LEVELS:	See attached.	UNION:	None
SPECIFY TYPE(S) OF INGREDIENT(S) PRODUCED/SUPPLIED BY THE SITE AND THEIR INTENDED APPLICATIONS:	The main products produced include enzymes, proteins, peptones, and flavors. These products are used in the food processing, pharmaceutical, veterinary health, nutritional, and companion animal industries. All products are sold in bulk form (typically 50 kg drums) and are for further manufacturing or repackaging use.		
SITE ACTIVITIES CONDUCTED:	Manufacturing/Processing/Blending/Packaging/Microbial & Chemical Testing/Warehousing/Shipping		
ORGANIZATIONAL CHART:	See attached.		
NUMBER OF EMPLOYEES & SHIFTS:	Approximately 135 Employees and one extended shift.		

### Section 2. EVIDENCE OF COMPLIANCE

ISO CERTIFICATION:	None
OTHER CERTIFICATIONS OR EXTERNAL AUDIT PROGRAMS:	FDA Establishment # 1920841 USDA Establishment #5805A/22043
LAST FDA OR STATE AGENCY cGMP INSPECTION (DATE) & OUTCOME:	November 2017, 483 resolved and closed

### Section 3. cGMP COMPLIANCE DETAILS

cGMP Compliance Details (for Food Grade Products produced by ALI):

American Laboratories Inc. (ALI) has in place an extensive Standard Operating Procedure (SOP) system governing all applicable elements of the current Good Manufacturing Practice (cGMP) in Manufacturing, Packing, or Holding Human Food (cGMP, 21 CFR part 110), Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (cGMP, 21 CFR part 117) and Guidance for Industry, Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.

All personnel receive cGMP training “at hire” and at least annually thereafter. Our personnel possess adequate education, experience, and/or training to perform all necessary functions. Any personnel health issues are reported to and evaluated by our Quality Assurance (QA) unit before allowing employees back to work. Our facilities and grounds are maintained by a qualified maintenance staff. Maintenance utilizes a comprehensive computerized Preventative Maintenance (PM) program. Our facilities and equipment are of sufficient design to perform all intended tasks/functions. We maintain an internal/external Pest Control program to control both insects and rodents. All lighting and ventilation are adequate to ensure a safe, clean, and efficient workplace. Equipment and utensils are maintained to ensure all food contact surfaces can be cleaned and sanitized to prevent adulteration of foodstuffs. Facilities plumbing and drainage/sewage control are adequate to ensure sanitary conditions. Potable water meeting U.S. EPA, State, and Municipal drinking water standards is used in our process operations, hand washing stations, and restroom areas. All equipment, freezers, coolers, calibrated process monitoring devices; pumps etc. are adequate in design to perform the intended functions. All processes are supervised by trained and experienced Production Supervisors and monitored by QA staff to ensure sanitary conditions are maintained to prevent adulteration of product. Our Finished Goods are stored in an environmentally monitored warehouse prior to distribution.

**Section 4. ADDITIONAL INFORMATION**

HACCP:	Yes, for applicable USDA amenable meat products.
CORPORATE BIOTERRORISM ACT COMPLIANCE:	Bioterrorism Registration Numbers: "Building 10" – 18586114626 "Building 36" – 17368762888
MEMBERSHIP IN INDUSTRY TRADE GROUPS:	NNFA, DCAT, ASM, AAPS, ETA, USP Advisory Panel Member, IFT, University of Nebraska Food Processing Center Advisory Board
YEAR INCORPORATED:	1967
TAX ID NUMBER:	47-0519792
W9:	See attached.

**Section 5. CONTACT INFORMATION**

COMPANY NAME:	American Laboratories, Inc.	PHONE/FAX:	Home office: 402-339-2494/402-339-0801 Purchasing/Sales: 402-858-2612
WEBSITE:	www.americanlaboratories.com	EMAIL:	sales@americanlaboratories.com
CONTACT NAME:	Jamie Deloske	TITLE:	Sales Operations Manager
CONTACT NAME:	Amanda Brown	TITLE:	Global Sales Manager
CONTACT NAME:	John Garcia	TITLE:	Director of Sales
CONTACT NAME:	Matthew Costanzo	TITLE:	Director of Regulatory Affairs
CONTACT NAME:	Jim McFayden	TITLE:	Vice President - Manufacturing
CONTACT NAME:	Rick Roswick	TITLE:	Vice President - Quality
CONTACT NAME:	Jan Giwoyna	TITLE:	Vice President - Administration
CONTACT NAME:	John Schneider	TITLE:	Vice President - Engineering
CONTACT NAME:	Rod Schake	TITLE:	Senior Vice President
CONTACT NAME:	Steven Pfeiffer	TITLE:	Chief Operating Officer
CONTACT NAME:	Jon Peppmuller	TITLE:	Chief Financial Officer
CONTACT NAME:	Kenny Soejoto	TITLE:	President