



National Animal Supplement Council



**Preferred Supplier Data Sheet (PSDS) for
Raw Material Suppliers and Contract Manufacturers**

All Raw Material Suppliers and Contract Manufacturers must provide the information requested in this form as part of the qualification procedure for acceptance as a Preferred Supplier by NASC. Any fields not applicable to your company should be completed by entering N/A.

Please return copies of the completed form(s) and requested certifications electronically to Bill Parker at b.parker@nasc.cc or mail to:

NASC
PO Box 5168
Sun City West, AZ 85376

This information will be posted in the Members Section of the NASC Web Site for companies to download for use in qualifying and accepting the supplier.

Questions: contact Bill Parker at the NASC office (760-751-3360 X105)

SECTION 1: SITE OVERVIEW			
NAME AND ADDRESS OF COMPANY OR SITE RESPONSIBLE:	BIO-CAT, Inc. 9117 Three Notch Rd. Troy, VA 22974		
WEB SITE:	www.bio-cat.com		
CONTACT PERSON	Mark Walin		
TELEPHONE NUMBER:	(434) 589-4777		
E-MAIL:	MWalin@bio-cat.com		
BUSINESS DESCRIPTION / SITE DETAILS:			
<p>With an emphasis on customization, BIO-CAT produces enzyme blends for use as ingredients in industrial, food, feed, and dietary supplement applications.</p> <p>Located inside of this 94,500 square foot facility are nine individual blending room, each containing one or more V-style blender. The facility also houses an on-site QC laboratory where the majority of required testing is performed on both incoming and custom blended materials. Family owned and operated since inception, BIO-CAT remains committed to continual improvements within our quality and food safety system standards to ensure that our customers continue to receive the highest degree of excellence offered in the industry.</p>			
FACILITY SIZE / # EMPLOYEES:	94,500 sq.ft., ~60 employees	DATE EST:	1988
GENERAL AND PRODUCT LIABILITY INSURANCE LEVELS:	General-\$1,000,000 Product - \$3,000,000 per occurrence	UNION:	N/A
SPECIFY TYPE(S) OF INGREDIENT(S), MANUFACTURING CAPABILITIES, PRODUCTS PRODUCED/SUPPLIED BY THE SITE, SERVICES AND THEIR INTENDED APPLICATIONS:	<p>Industrial, Food, Feed, Dietary Supplements – Given the custom nature of our business, our products are used as ingredients across all industries.</p> <p>We have 12 V-blenders for powdered products, our largest being 120 cu.ft.</p>		
SITE ACTIVITIES CONDUCTED:	Custom mixing of powdered enzymes and probiotics.		
ORGANIZATIONAL CHART:	See attached		



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SECTION 2: EVIDENCE OF COMPLIANCE	
INDEPENDENT QUALITY CERTIFICATIONS:	Yes IF YES, SPECIFY: FSSC 22000:2018 v5.1, 21 CFR Part 117 GMP Certified, registered with the FDA as an ingredient manufacturer and re-packer
QUALITY MANAGEMENT SYSTEM STANDARD:	FSSC 22000:2018 v.5.1
APPROVAL CERTIFICATES:	See attached
NUMBER AND NAME OF REGISTRAR WHO PROVIDED CERTIFICATE OF APPROVAL:	SGS North America (201) 508-3000
OTHER CERTIFICATIONS OR EXTERNAL AUDIT PROGRAMS:	GMP Certified through SGS
WEB SITE:	
DATE OF LAST FDA OR STATE AGENCY CGMP INSPECTION AND OUTCOME (PROVIDE COPY OF REPORT OF OBSERVATIONS FROM LAST FDA OR STATE INSPECTION):	FDA/VDACS on behalf of FDA: 05/17/2022 Report attached.

SECTION 3: RAW MATERIAL SUPPLIERS & CONTRACT MANUFACTURERS ONLY	
DO YOU HAVE Q/C RELEASE REQUIREMENTS FOR ALL SHIPMENTS WHEN THEY ARRIVE: (YES / NO)	Yes
DO YOU SAMPLE EVERY LOT OF RAW MATERIALS RECEIVED: (YES / NO)	Yes
DO YOU RE-PACK LARGE QUANTITIES INTO SMALLER QUANTITIES AT YOUR FACILITY: (YES / NO)	Yes
DO YOU SAMPLE EVERY LOT: (YES / NO)	Yes
DO YOU PERFORM ANY BLENDING AT YOUR FACILITY (YES / NO)	Yes
LIST ALL INGREDIENTS HELD AT YOUR FACILITY (ATTACH A LIST/DOCUMENT IF AVAILABLE: (YES / NO))	
PHARMACEUTICAL:	No
NUTRITIONAL:	No
BOTANICAL:	No
MINERAL:	No
ENZYME:	Yes – <i>line added below</i>
Acid Protease, Alpha-Galactosidase, Amylase, Amyloglucosidase, Bacterial Amylase, Bacterial Protease, Beta-Glucanase, Bromelain, Cellulase, Diastase, Fungal Amylase, Fungal Lactase, Fungal Lipase, Fungal Protease, Galactomannanase, Hemicellulase, Invertase, Lactase, Lipase, Malt Diastase, Maltase, Neutral Bacterial Protease, Neutral Protease, Peptidase, Phytase, Protease, Xylanase, Yeast Lipase	
HORMONE:	No
PROBIOTIC:	Yes – <i>Lactobacillus acidophilus, Bifidobacterium bifidum, Bifidobacterium lactis</i>
CHEMICAL (OTHER):	Diluents listed below
Additional Ingredients: Calcium carbonate, Calcium lactate, Cassava dextrin, D-mannitol, Dextrin, Dextrose, Dicalcium phosphate, Glycerol, Maltodextrin from waxy maize, Potato dextrin, Silicon dioxide, Sodium acetate, Sodium benzoate, Sodium chloride, Sodium metabisulfite, Starch, Tapioca dextrin, Tapioca maltodextrin, Yeast nutrex	
METHODS CONDUCTED IN FACILITY: (YES / NO)	
DO YOU USE AN IN-HOUSE LOT NUMBERING SYSTEM?	Yes
DO YOU EVER MIX MULTIPLE LOTS OF THE SAME INGREDIENT WHEN YOU BLEND?	Yes, if necessary
TESTING INFORMATION:	
IF YOU RELY ON BOTH IN-HOUSE AND OUTSIDE CONTRACT LABS, PLEASE FILL OUT BOTH SECTIONS	
DOES THIS FACILITY RELY ON AN <u>IN-HOUSE</u> LAB? (YES / NO)	Yes



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IN-HOUSE TESTS PERFORMED: (YES / NO)	Yes
POTENCY ASSAY OF RAW MATERIALS? (YES / NO)	Yes
RAW MATERIAL ASSAY? (YES / NO)	Yes
MICROBIAL? (YES / NO – IF YES SPECIFY)	Yes – TPC, Y&M, Coliforms, E.coli, Salmonella
pH? (YES / NO)	Yes
MOISTURE? (YES / NO)	Yes
ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	No
HEAVY METALS? (YES / NO – IF YES SPECIFY)	No
OTHER? (YES / NO – IF YES SPECIFY)	Yes – FTIR identity
IF YOU HAVE AN IN-HOUSE LAB PLEASE SPECIFY WHICH LAB ACCREDITATION ORGANIZATION(S) YOU ARE AFFILIATED WITH:	None at this time

OUTSIDE CONTRACT LABS USED	
PLEASE LIST YOUR MOST FREQUENTLY USED CONTRACT LABS AND THEIR ACCREDITATION STATUS: (e.g., ISO, FDA, USDA, AOAC, USP, NSF, NPA, A2LA, ANSI, ETC.) *PLEASE PROVIDE ACCREDITATION NUMBER*	
NAME OF LAB #1:	SORA Laboratories, LLC
ADDRESS / LOCATION:	15366 US Highway 160 Forsyth, MO 65653
CONTACT NAME / PHONE NUMBER:	Tammy Blakemore, (877) 645-8767
LIST ANY CERTIFICATIONS FOR THE LAB:	ISO 17025
TESTING PERFORMED BY THE OUTSIDE LAB:	
POTENCY ASSAY OF RAW MATERIALS? (YES / NO)	Yes – on occasion, as necessary for proficiency testing
RAW MATERIAL ASSAY? (YES / NO)	Yes – see comment above
MICROBIAL? (YES / NO – IF YES SPECIFY)	No
pH? (YES / NO)	No
MOISTURE? (YES / NO)	No
ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	No
HEAVY METALS? (YES / NO – IF YES SPECIFY)	Yes – Arsenic, Cadmium, Lead, Mercury
OTHER? (YES / NO – IF YES SPECIFY)	No
NAME OF LAB #2:	
ADDRESS / LOCATION:	Analytical Resource Laboratories 520 South 850 East, Suite B3 Lehi, UT 84043
CONTACT NAME / PHONE NUMBER:	Renee Tran, (801) 847-7722
LIST ANY CERTIFICATIONS FOR THE LAB:	ISO 17025
TESTING PERFORMED BY THE OUTSIDE LAB:	
POTENCY ASSAY OF RAW MATERIALS? (YES / NO)	No
RAW MATERIAL ASSAY? (YES / NO)	No
MICROBIAL? (YES / NO – IF YES SPECIFY)	No
pH? (YES / NO)	No
MOISTURE? (YES / NO)	No
ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	No
HEAVY METALS? (YES / NO – IF YES SPECIFY)	Yes – Arsenic, Cadmium, Lead, Mercury
OTHER? (YES / NO – IF YES SPECIFY)	No



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NAME OF LAB #3:	N/A
ADDRESS / LOCATION:	
CONTACT NAME / PHONE NUMBER:	
LIST ANY CERTIFICATIONS FOR THE LAB:	
TESTING PERFORMED BY THE OUTSIDE LAB:	
POTENCY ASSAY OF RAW MATERIALS? (YES / NO)	
RAW MATERIAL ASSAY? (YES / NO)	
MICROBIAL? (YES / NO – IF YES SPECIFY)	
pH? (YES / NO)	
MOISTURE? (YES / NO)	
ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	
HEAVY METALS? (YES / NO – IF YES SPECIFY)	
OTHER? (YES / NO – IF YES SPECIFY)	

SECTION 4: CGMP COMPLIANCE DETAILS

PROVIDE A BRIEF SUMMARY OF HOW THE SUPPLIER COMPLIES WITH EACH APPLICABLE ELEMENT OF THE CURRENT GMP GUIDELINES. NON-APPLICABLE ELEMENTS SHOULD BE NOTED AS SUCH.

From personal cleanliness to good documentation practices, BIO-CAT has SOPs in place to ensure all aspects of current GMPs are abided by.

Throughout the production area hand washing stations and sanitizer is readily available. To avoid potential contamination by foreign material, artificial nails, nail polish, jewelry, glitter, etc. are not permitted. Food and drink must be kept in the designated employee lunch room and personal items in assigned employee lockers. These items are not allowed in the manufacturing area. New shoes are purchased for all production employees upon hire and as needed thereafter. An employee's street shoes are to be removed and placed on racks by the entrance to minimize the risk of contamination by an outside source. Waterproof boots are purchased for production employees upon hire and as needed thereafter. These are to be worn inside blending areas during blending operations and cleaning.

Production employees must wear appropriate PPE during blending. Full garbing includes a disposable Tyvek suit, assigned full-face respirator, boots, colored gloves, arm protectors, and bouffant hats. All blending operations are witnessed and signed off on by two employees, the pairing of which is on a rotating schedule. It is the responsibility of each production employee to monitor their areas, keeping them tidy and free of clutter and trash. This includes proper labeling of all containers.

Visitors must register at the front desk and receive a pass in order to access the facility. These individuals must abide by BIO-CAT's visitor policy and be accompanied by an employee at all times.

All BIO-CAT employees must follow good documentation practices, including the appropriate way to correct any written mistake. White out is not permitted for use.

IS FACILITY ISO CERTIFIED? YES / NO: IF YES SPECIFY THE ISO STANDARD AND ATTACH CURRENT CERTIFICATE.	Yes – FSSC 22000:2018 v.5.1 is also referred to as ISO 22000
LIST AND ATTACH ANY OTHER CERTIFICATIONS OR EXTERNAL AUDIT PROGRAMS (E.G., NSF, USP, NPA, ISO, ETC.):	

SPECIFY MOST RECENT FACILITY INSPECTIONS BY STATE, FEDERAL, OR
FOREIGN AGENCY (DATE OF INSPECTION, AND RESULTS OF THE INSPECTION SPECIFY AGENCY):

DATE	INSPECTION AGENCY	RESULTS OF THE INSPECTION
10/10 - 10/11/2023	SGS	FSSC 22000 v.5.1 certification issued – PASS
10/10 - 10/11/2023	SGS	GMP certification issued – PASS
05/17/2022	FDA	21 CFR 117 – PASS
05/22/2023	IFANCA	Halal certification issued – PASS
04/26/2023	OU	Kosher certification issued – PASS



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SECTION 5: ADDITIONAL INFORMATION

Hazard Plan (HACCP) / DATE IMPLEMENTED:	10/09/2023
STATISTICAL PROCESS CONTROL/PROCESS ANALYTICAL CONTROL:	
CORPORATE BIOTERRORISM ACT COMPLIANCE:	Our facility is registered with the FDA in accordance with the Bio-Terrorism Act implemented in 2002. The last 5 digits of our registration number are --64078.
DESCRIBE ALL MEASURES TAKEN BY FACILITY TO ENSURE PRODUCT QUALITY AND PRODUCT CONTAMINATION PREVENTION.	<p>Every supplier and every raw material is evaluated prior to purchase. If approved and purchased, every lot is sampled upon arrival using the square root of N+1 sampling rule. Samples are submitted to QC for analysis, which includes activity, moisture, color, and FTIR identity. The first 5 lots of every raw material are submitted for full micro and sent to SORA for heavy metals testing. Upon receipt of passing results for the first 5 lots, every fifth lot is submitted for full micro and metals testing thereafter. Although received in the facility, a product is not available for use until it is released by QA. During testing, materials stay on "QC Hold" and are quarantined from product available for use in the warehouse.</p> <p>There are primary and side activities for the majority of enzymes. At BIO-CAT, we test the primary activity unit 4 times, then use an average of those numbers to blend customer products. Doing this allows us to better hone in on the true batch activity from a vendor, thus blend better quality material for customers. Once released from QA, the material becomes active in BIO-CAT inventory and can be used in blending. To minimize the risk of foreign object contamination, production employees complete a check-in/check-out log for each room, each day. Tags from containers, zip ties, etc. are listed on this document and must be accounted for after each blend. This is witnessed and signed off on by two employees.</p> <p>Each blending room is equipped with its own air handling system which includes a pre-filter and box filter. Individual air units help to eliminate the risk of cross-contamination from room to room.</p>
MEMBERSHIP IN INDUSTRY TRADE GROUPS:	

SECTION 6: CONTRACT MANUFACTURERS

HOW DO YOU GUARANTEE BANNED SUBSTANCES (STIMULANTS, NARCOTICS, STEROIDS, DIURETICS, BETA-2-AGONISTS, BETA BLOCKERS, MASKING AGENTS, OR SIMILAR SUBSTANCES) ARE NOT PRESENT IN YOUR INGREDIENTS?	Prior to purchase from any supplier, they must first be qualified. In addition, each of the materials to be purchased must also be qualified prior to placing an order. Part of this process includes sampling and testing, while part of it involves questionnaires. Included are queries about banned substances, antibiotics, synthetic materials, solvents, melamine, etc.
HOW DO YOU QUALIFY AN INGREDIENT MANUFACTURER?	Through review of their quality system and a completed questionnaire regarding operations and procedures. An on-site audit of their facility will also take place, either conducted by BIO-CAT or a third-party certification body on behalf of BIO-CAT. Vendors are also reviewed annually and receive scorecards. This review encompasses all departments and requires details surrounding finance, shipping, sales and innovation, communication, and a food fraud risk analysis.



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SECTION 7: AUTHENTICITY OF INFORMATION & CONTACT INFORMATION

COMPANY NAME:	BIO-CAT, Inc.		
CONTACT NAME:	Kacy Perkins	TITLE:	Lead Compliance Associate
E-MAIL ADDRESS:	knp@bio-cat.com		

BY SIGNING BELOW, I CERTIFY THAT THE INFORMATION GIVEN BY ME TO THE NATIONAL ANIMAL SUPPLEMENT COUNCIL (NASC), INC. IS TRUE AND COMPLETE TO THE BEST OF MY KNOWLEDGE. I UNDERSTAND THAT IF THE INFORMATION PROVIDED IS NOT THOROUGH AND COMPLETE, NASC WILL REJECT THE FORM AND RESUBMISSION OF THE FORM WILL BE REQUIRED.

	11/17/2023
SIGNATURE	DATE