



National Animal Supplement Council



Preferred Supplier Non-Botanical Ingredient Data Sheet (N-BIDS)

NASC established a **Preferred Supplier Program** for companies who wish to provide products and services to NASC member companies, including raw materials (ingredients), contract manufacturing (dosage form products and feed supplements), analytical laboratory services and other services such as insurance, business consulting, legal expertise, etc.

The goal of the program is to prequalify vendors so that NASC members may accept and use products or services from Preferred Suppliers without additional vendor qualification procedures required under NASC cGMPs.

There are four categories of **NASC Preferred Suppliers**: Raw Material Suppliers, Contract Manufacturers, Analytical Laboratories and Service Providers.

The qualification procedure includes providing information to NASC on the scope of company operations, quality compliance program certifications, statements and additional documentation specific to the type of supplier, e.g., data sheets for each ingredient a Raw Material Supplier would like to qualify and include in the program.

Preferred Supplier Non-Botanical Ingredient Data Sheet

All Raw Material Suppliers must provide the information requested in this form as part of the qualification procedure for a single non-botanical ingredient. Any fields not applicable to the company or ingredient should be completed by entering N/A.

Please return copies of the requested certifications and the completed form electronically to Bill Bookout at b.bookout@nasc.cc or mail to:

NASC
PO Box 2568
Valley Center, CA 92082

Contact Bill Bookout at the NASC office (760-751-3360) with any questions about the **Preferred Supplier Program**.



National Animal Supplement Council



Preferred Supplier Non-Botanical Ingredient Data Sheet (N-BIDS)

SECTION 1. INGREDIENT & SUPPLIER INFORMATION

SUPPLIER (COMPANY) PROVIDING INGREDIENT:	Metabolic Technologies, Inc.
INGREDIENT NAME & CODE:	Calcium β -hydroxy- β -methylbutyrate monohydrate
GENERAL INGREDIENT INFORMATION:	HMB

SECTION 2. MANUFACTURING INFORMATION

NAME AND ADDRESS OF MANUFACTURING SITE:	Jiangyin TSI Pharmaceutical Co., Ltd. Jiangyin, China
MODE OF MANUFACTURING	Chemical Synthesis
DESCRIBE MANUFACTURING PROCESS (ATTACH FLOW CHART IF AVAILABLE):	Contact Metabolic Technologies, Inc. 515-296-9916
STERILIZATION OF FUMIGATION METHOD(S):	N/A
KNOWN OR POTENTIAL SOURCES OF IMPURITIES AND/OR CONTAMINANTS:	Dedicated plant virtually eliminates possibilities for contaminants

SECTION 3. INGREDIENT PHYSICAL / CHEMICAL INFORMATION

COMMON OR USUAL NAME / OTHER NAMES:	HMB; calcium HMB
EXAMPLE OF CURRENT PRODUCT SPECIFICATION SHEET / CERTIFICATE OF ANALYSIS ATTACHED:	Contact Metabolic Technologies, Inc. 515-296-9916
% ACTIVE INGREDIENT:	See Specification Sheet or C of A
BIOASSAY METHOD (SPECIFY):	N/A
PHYSICAL FORM OF THE INGREDIENT:	Powder
PARTICLE SIZE:	See Specification Sheet or C of A
COUNTRY OF ORIGIN:	China



Preferred Supplier Non-Botanical Ingredient Data Sheet (N-BIDS)

SECTION 4. REGULATORY & LABELING INFORMATION

PATENT COVERAGE:		US Patent 6,103,764 and corresponding international patents
GMP COMPLIANCE STANDARDS FOLLOWED (CITE):		21 CFR 111
IDENTIFY THE CRITICAL CONTROL POINTS THAT ARE MONITORED TO MAINTAIN GMP'S		Plant is NSF GMP Certified
LIST ANY CERTIFICATIONS OR EXTERNAL AUDIT PROGRAMS (E.G., NSF, USP, NPA, ISO, ETC.):		NSF
DATE & AGENCY OF MOST RECENT FACILITY INSPECTIONS (STATE, FEDERAL, OR FOREIGN AGENCY):		
DATE	INSPECTION AGENCY	RESULTS OF INSPECTION
Feb 23, 2011	FDA	NAI
FEED / FOOD INGREDIENT: AAFCO APPROVED YES / NO:		
		No
HOW INGREDIENT IS LISTED IN THE AAFCO OFFICIAL PUBLICATION:		
		N/A
EXAMPLE OF CURRENT PRODUCT SPECIFICATION SHEET / CERTIFICATE OF ANALYSIS ATTACHED:		
		Contact Metabolic Technologies, Inc. 515-296-9916
BIOASSAY METHOD (SPECIFY):		
		N/A
ANIMAL HEALTH INGREDIENT: EXAMPLES OF STRUCTURE FUNCTION CLAIMS SUPPORTED BY RESEARCH / CLINICAL STUDIES		
		Supports improved performance
TARIFF CODE FOR IMPORT/EXPORT:		
		N/A
ANY KNOWN RESTRICTIONS FOR USE IN OR WARNINGS FOR ANIMALS?		
		Not for use in animals intended for food
ANY INTERACTION WITH OTHER INGREDIENTS OR DRUGS TO AVOID?		
		N/A



Preferred Supplier Non-Botanical Ingredient Data Sheet (N-BIDS)

SECTION 5 SUPPORTING DOCUMENTATION

ATTACH ANY STATEMENT FOR THE INGREDIENT THAT ARE APPLICABLE TO THIS INGREDIENT.

Table with 2 columns: EXAMPLES and ATTACHED: YES / NO / N-A. Rows include KOSHER / HALAL STATEMENT, IRRADIATION STATEMENT, ETO STATEMENT, GMO STATEMENT, MSDS SHEET, HORMONE STATEMENT, BSE / TSE STATEMENT, ORGANIC CERTIFICATION STATEMENT, CURRENT PRODUCT DATA SHEET, MANUFACTURING PROCESS FLOW CHART, STABILITY DATA, MATERIAL EVALUATION FORM, and COUNTRY OF ORIGIN STATEMENT.

SECTION 6. ADDITIONAL INGREDIENT INFORMATION

Table with 2 columns: RECOMMENDED STORAGE CONDITIONS and ADDITIONAL COMMENTS / INFORMATION. Values: Keep closed and sealed/non-specific conditions; none.

SECTION 7. CONTACT INFORMATION

Table with 2 columns: CONTACT NAME, TITLE, OFFICE PHONE, OTHER PHONE, E-MAIL. Values: John C. Fuller, Jr., PhD; Research Scientist; 515-296-8065; 515-296-9916; Fuller@mti-hmb.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.

Table with 2 columns: SIGNATURE and DATE. Signature: John C. Fuller, Jr.; Date: 19-May-2015.