



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.

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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 Parker at b.parker@nasc.cc or mail to:

NASC
PO Box 5168
Sun City West, AZ 85376

Contact Bill Parker at the NASC office (760-751-3360, X105) with any questions about the **Preferred Supplier Program**.

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SECTION 1. INGREDIENT & SUPPLIER INFORMATION

SUPPLIER (COMPANY) PROVIDING INGREDIENT:	Ingredia Inc.
INGREDIENT NAME & CODE:	Lactium®
GENERAL INGREDIENT INFORMATION:	Dried Hydrolyzed Casein

SECTION 2. MANUFACTURING INFORMATION

NAME AND ADDRESS OF MANUFACTURING SITE:	Ingredia ZI Route d'Ostreville 62130 St Pol Sur Ternoise, France
MODE OF MANUFACTURING	Casein separation, enzymatic hydrolysis, spray-drying See Flowchart attached
DESCRIBE MANUFACTURING PROCESS (ATTACH FLOW CHART IF AVAILABLE):	See flow chart attached
STERILIZATION OF FUMIGATION METHOD(S):	Heat Treatment
KNOWN OR POTENTIAL SOURCES OF IMPURITIES AND/OR CONTAMINANTS:	Conforms to EU regulations

SECTION 3. INGREDIENT PHYSICAL / CHEMICAL INFORMATION

COMMON OR USUAL NAME / OTHER NAMES:	Dried Hydrolyzed Milk Casein
EXAMPLE OF CURRENT PRODUCT SPECIFICATION SHEET / CERTIFICATE OF ANALYSIS ATTACHED:	See Technical Data Sheet and COA Example attached
% ACTIVE INGREDIENT:	≥ 1.8 %
BIOASSAY METHOD (SPECIFY):	α-s1-Cn (f91-100)
PHYSICAL FORM OF THE INGREDIENT:	Dairy/Milk Powder
PARTICLE SIZE:	Data not available
COUNTRY OF ORIGIN:	France

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SECTION 4. REGULATORY & LABELING INFORMATION

PATENT COVERAGE:	<p>Ingredia France owns a patent on the decapeptide and its activity, including the products containing it.</p> <p>The European title is: Use of the decapeptide with benzodiazepine activity for the preparation of medicaments and dietary supplements. EP0714910B1, Nov. 30, 1995.</p> <p>The US Title is: Use of a decapeptide with benzodiazepine-type activity for preparing medicines and food supplements. Patent Number 5,846,939, Dec. 8, 1998.</p> <p>The Japan Title is: The use of decapeptide with benzodiazepine-type activity for preparing medicines. Patent number 3973244, June 22, 2007.</p>	
GMP COMPLIANCE STANDARDS FOLLOWED (CITE):	GMP+FC Scheme CERTIS	
IDENTIFY THE CRITICAL CONTROL POINTS THAT ARE MONITORED TO MAINTAIN GMP'S	Heat Treatment 72°/15s or equivalent, Sieve 2mm (two locations in system), Metal Detector FE=3mm, Non-FE=4mm, SS=3.4mm See Flowchart attached	
LIST ANY CERTIFICATIONS OR EXTERNAL AUDIT PROGRAMS (E.G., NSF, USP, NPA, ISO, ETC.):	GMP+FC Scheme FSSC 22000 ISO 9001 See Certificates attached	
DATE & AGENCY OF MOST RECENT FACILITY INSPECTIONS (STATE, FEDERAL, OR FOREIGN AGENCY):		
DATE	INSPECTION AGENCY	RESULTS OF INSPECTION
12/07/2012	FDA	Satisfactory
FEED / FOOD INGREDIENT: AAFCO APPROVED YES / NO:	Yes	
HOW INGREDIENT IS LISTED IN THE AAFCO OFFICIAL PUBLICATION:	Dried Hydrolyzed Casein	
EXAMPLE OF CURRENT PRODUCT SPECIFICATION SHEET / CERTIFICATE OF ANALYSIS ATTACHED:	See Technical Data Sheet and COA Example attached	
BIOASSAY METHOD (SPECIFY):	α-s1-Cn (f91-100)	
ANIMAL HEALTH INGREDIENT:	Helps reduce stress related symptoms	



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EXAMPLES OF STRUCTURE FUNCTION CLAIMS SUPPORTED BY RESEARCH / CLINICAL STUDIES	Helps promote a healthy calming sleep due to stress reduction Helps improve the quality of sleep
TARIFF CODE FOR IMPORT/EXPORT:	35.04.00.90.00
ANY KNOWN RESTRICTIONS FOR USE IN OR WARNINGS FOR ANIMALS?	No
ANY INTERACTION WITH OTHER INGREDIENTS OR DRUGS TO AVOID?	No known interactions to avoid



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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: Ambient, cool and dry; N/A.

SECTION 7. CONTACT INFORMATION

Table with 2 columns: CONTACT NAME, TITLE, OFFICE PHONE, OTHER PHONE, E-MAIL. Values: Andrea Hale, Quality Manager, 419-738-4060, 419-296-6812, a.hale@ingredia.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. Values: [Handwritten Signature], 12/07/2022