



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 5168
Sun City West, AZ 85376

Contact Bill Bookout at the NASC office (760-751-3360, X1) with any questions about the **Preferred Supplier Program**.

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SECTION 1. INGREDIENT & SUPPLIER INFORMATION

SUPPLIER (COMPANY) PROVIDING INGREDIENT:	Wacker Chemical Corporation
INGREDIENT NAME & CODE:	CAVAMAX® W6 Food Alpha cyclodextrin (60071344), CAVAMAX® W8 Food Gamma cyclodextrin (60071379)
GENERAL INGREDIENT INFORMATION:	Alpha cyclodextrin; Gamma cyclodextrin

SECTION 2. MANUFACTURING INFORMATION

NAME AND ADDRESS OF MANUFACTURING SITE:	Wacker Chemical Corporation
MODE OF MANUFACTURING	Enzymatic conversion (Continuous process)
DESCRIBE MANUFACTURING PROCESS (ATTACH FLOW CHART IF AVAILABLE):	please see flow sheets
STERILIZATION OF FUMIGATION METHOD(S):	N/A
KNOWN OR POTENTIAL SOURCES OF IMPURITIES AND/OR CONTAMINANTS:	please see certificate of analysis

SECTION 3. INGREDIENT PHYSICAL / CHEMICAL INFORMATION

COMMON OR USUAL NAME / OTHER NAMES:	CAVAMAX W6, CAVAMAX W8
EXAMPLE OF CURRENT PRODUCT SPECIFICATION SHEET / CERTIFICATE OF ANALYSIS ATTACHED:	refer to certificate of analysis
% ACTIVE INGREDIENT:	see composition information
BIOASSAY METHOD (SPECIFY):	HPLC
PHYSICAL FORM OF THE INGREDIENT:	powder
PARTICLE SIZE:	Bulk density 400 - 700 kg/m ³
COUNTRY OF ORIGIN:	USA

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SECTION 4. REGULATORY & LABELING INFORMATION

PATENT COVERAGE:		
GMP COMPLIANCE STANDARDS FOLLOWED (CITE):		21 CFR 117
IDENTIFY THE CRITICAL CONTROL POINTS THAT ARE MONITORED TO MAINTAIN GMP'S		Refer to flow sheet
LIST ANY CERTIFICATIONS OR EXTERNAL AUDIT PROGRAMS (E.G., NSF, USP, NPA, ISO, ETC.):		ISO 9001:2015; ISO 14001:2015; FSSC 22000
DATE & AGENCY OF MOST RECENT FACILITY INSPECTIONS (STATE, FEDERAL, OR FOREIGN AGENCY):		
DATE	INSPECTION AGENCY	RESULTS OF INSPECTION
08.16 and 08.18.2017	FDA (contacted to Iowa Dept of Inspections)	No 483 issued
FEED / FOOD INGREDIENT: AAFCO APPROVED YES / NO:		no
HOW INGREDIENT IS LISTED IN THE AAFCO OFFICIAL PUBLICATION:		
EXAMPLE OF CURRENT PRODUCT SPECIFICATION SHEET / CERTIFICATE OF ANALYSIS ATTACHED:		see Technical Data Sheet
BIOASSAY METHOD (SPECIFY):		
ANIMAL HEALTH INGREDIENT: EXAMPLES OF STRUCTURE FUNCTION CLAIMS SUPPORTED BY RESEARCH / CLINICAL STUDIES		
TARIFF CODE FOR IMPORT/EXPORT:		2940.00.6000
ANY KNOWN RESTRICTIONS FOR USE IN OR WARNINGS FOR ANIMALS?		no
ANY INTERACTION WITH OTHER INGREDIENTS OR DRUGS TO AVOID?		

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SECTION. 5 SUPPORTING DOCUMENTATION

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

<u>EXAMPLES</u>	<u>ATTACHED: YES / NO / N-A</u>
• KOSHER / HALAL STATEMENT	yes
• IRRADIATION STATEMENT	yes
• ETO STATEMENT	yes
• GMO STATEMENT	yes
• MSDS SHEET	yes
• HORMONE STATEMENT	N/A
• BSE / TSE STATEMENT	yes
• ORGANIC CERTIFICATION STATEMENT	N/A
• CURRENT PRODUCT DATA SHEET	yes
• MANUFACTURING PROCESS FLOW CHART	yes
• STABILITY DATA	yes
• MATERIAL EVALUATION FORM	
• COUNTRY OF ORIGIN STATEMENT	yes


SECTION 6. ADDITIONAL INGREDIENT INFORMATION

RECOMMENDED STORAGE CONDITIONS:	36 months
ADDITIONAL COMMENTS / INFORMATION:	storage at room temperature in sealed containers is recommended

SECTION 7. CONTACT INFORMATION

CONTACT NAME:	Dr. Cornelia Ciosto
TITLE:	Senior Manager Quality Assurance & Regulatory Affairs, Quality Management
OFFICE PHONE:	+498962791694
OTHER PHONE:	
E-MAIL:	cornelia.ciosto@wacker.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.

	April 15 th , 2020
SIGNATURE	DATE



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