



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 Bookout at b.bookout@nasc.cc or mail to:

NASC
PO Box 2568
Valley Center, CA 92082

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 Bookout at the NASC office (760-751-3360)

SECTION 1: SITE OVERVIEW			
NAME AND ADDRESS OF COMPANY OR SITE RESPONSIBLE:	TROPICHEM RESEARCH LABS, LLC, 15843 GUILD COURT JUPITER, FL 33478		
WEB SITE:	WWW.TROPICHEM.COM		
CONTACT PERSON	MIKE SMITH		
TELEPHONE NUMBER:	314-397-1352		
E-MAIL:	MIKE.SMITH@TROPICHEM.COM		
BUSINESS DESCRIPTION / SITE DETAILS: LIQUID PRODUCT DEVELOPMENT AND MANUFACTURING INCLUDING APIs, WITH IN HOUSE LABORATORIES			
FACILITY SIZE / # EMPLOYEES:	30,000 sq. ft plus 15,000 additional warehouse	DATE EST:	BUILT IN 2008
GENERAL AND PRODUCT LIABILITY INSURANCE LEVELS:	\$2,000,000 GENERAL LIABILITY POLICY	UNION:	NO
SPECIFY TYPE(S) OF INGREDIENT(S), MANUFACTURING CAPABILITIES, PRODUCTS PRODUCED/SUPPLIED BY THE SITE, SERVICES AND THEIR INTENDED APPLICATIONS:	Medicated and Non-Medicated Liquids, Creams, Gels, Mousses, Sprays, Wipes. 6 high speed filling lines with automated labeling. 1oz to 1gallon fills, plus bulk. FDA and EPA site registration. Companion animal topical dermatological products for veterinary and retail channels.		
SITE ACTIVITIES CONDUCTED:	LIQUID PRODUCT DEVELOPMENT AND MANUFACTURING		
ORGANIZATIONAL CHART:	SEPARATE ATTACHMENT		

SECTION 2: EVIDENCE OF COMPLIANCE		
INDEPENDENT QUALITY CERTIFICATIONS:	NA IF YES, SPECIFY:	
	QUALITY MANAGEMENT SYSTEM STANDARD:	CFR 210 & 211
	APPROVAL CERTIFICATES:	FDA INSPECTION
	NUMBER AND NAME OF REGISTRAR WHO PROVIDED CERTIFICATE OF APPROVAL:	
OTHER CERTIFICATIONS OR EXTERNAL AUDIT PROGRAMS:	NA	
WEB SITE:	NA	
DATE OF LAST FDA OR STATE AGENCY CGMP INSPECTION AND OUTCOME (PROVIDE COPY OF REPORT OF OBSERVATIONS FROM LAST FDA OR STATE INSPECTION):	FDA, FEBRUARY 2017 (SEPARATE ATTACHMENT)	



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SECTION 3: RAW MATERIAL SUPPLIERS & CONTRACT MANUFACTURERS ONLY	
DO YOU HAVE Q/C RELEASE REQUIREMENTS FOR ALL SHIPMENTS WHEN THEY ARRIVE: (YES / NO)	ACTIVE RELEASE TESTING FOR ALL APIs, COA RELEASE FOR ALL OTHER
DO YOU SAMPLE EVERY LOT OF RAW MATERIALS RECEIVED: (YES / NO)	API ONLY
DO YOU RE-PACK LARGE QUANTITIES INTO SMALLER QUANTITIES AT YOUR FACILITY: (YES / NO)	NO
DO YOU SAMPLE EVERY LOT: (YES / NO)	YES FOR API
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:	YES
NUTRITIONAL:	YES
BOTANICAL:	YES
MINERAL:	YES
ENZYME:	YES
HORMONE:	NO
PROBIOTIC:	NO
CHEMICAL (OTHER):	YES, SURFACTANTS, ETC
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 NEEDED FOR FIFO, AS NOTED ON BATCH SHEET
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
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
pH? (YES / NO)	YES
MOISTURE? (YES / NO)	NO
ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	NO
HEAVY METALS? (YES / NO – IF YES SPECIFY)	NO
OTHER? (YES / NO – IF YES SPECIFY)	Viscosity, Density
IF YOU HAVE AN IN-HOUSE LAB PLEASE SPECIFY WHICH LAB ACCREDITATION ORGANIZATION(S) YOU ARE AFFILIATED WITH:	NA, OUTSIDE LAB USED FOR TESTS NEEDING ACCREDITATION



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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:	Q Laboratories, Inc.
ADDRESS / LOCATION:	1400 Harrison Ave. Cincinnati, OH 45214
CONTACT NAME / PHONE NUMBER:	Lauren Goins
LIST ANY CERTIFICATIONS FOR THE LAB:	ISO/IEC 17025:2005
TESTING PERFORMED BY THE OUTSIDE LAB:	
POTENCY ASSAY OF RAW MATERIALS? (YES / NO)	YES
RAW MATERIAL ASSAY? (YES / NO)	YES
MICROBIAL? (YES / NO – IF YES SPECIFY)	YES – USP 61/62, USP 39 <51>
pH? (YES / NO)	NO
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)	USP RAW MATERIAL TESTING AS NEEDED, WATER TESTING (TOC, CONDUCTIVITY, MICRO)
NAME OF LAB #2:	Microbac Laboratories, Inc.
ADDRESS / LOCATION:	3809 Airport Drive Wilson, NC 27896
CONTACT NAME / PHONE NUMBER:	Timothy Klock
LIST ANY CERTIFICATIONS FOR THE LAB:	A2LA – Foods Microbiology, A2LA – Chemical -AGR, US DEA, FDA, NC Drinking Water Microbiology
TESTING PERFORMED BY THE OUTSIDE LAB:	
POTENCY ASSAY OF RAW MATERIALS? (YES / NO)	NO
RAW MATERIAL ASSAY? (YES / NO)	
MICROBIAL? (YES / NO – IF YES SPECIFY)	YES – USP 61/62
pH? (YES / NO)	NO
MOISTURE? (YES / NO)	NO
ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	NO
HEAVY METALS? (YES / NO – IF YES SPECIFY)	NO
OTHER? (YES / NO – IF YES SPECIFY)	USP TESTING AS REQUESTED, CLEANING VALIDATION TESTING
NAME OF LAB #3:	
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)	



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ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	
HEAVY METALS? (YES / NO – IF YES SPECIFY)	
OTHER? (YES / NO – IF YES SPECIFY)	



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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.

FULLY AUTONOMOUS QUALITY GROUP WITH THE QUALITY MANUAL AVAILABLE UPON REQUEST.

IS FACILITY ISO CERTIFIED? YES / NO: IF YES SPECIFY THE ISO STANDARD AND ATTACH CURRENT CERTIFICATE.	NO
LIST AND ATTACH ANY OTHER CERTIFICATIONS OR EXTERNAL AUDIT PROGRAMS (E.G., NSF, USP, NPA, ISO, ETC.):	Canada GMP – BioMedex Audit, Florida – Over-the-Counter Drug Manufacture License, Florida – Cosmetic Manufacture License, EPA Registration

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
February 2017	FDA	483 – See Attached
March 2017	BiomedEx – Canada GMP	No Major Observations, Satisfactory Status
November 2016	Florida EPA	Satisfactory Status
April 2016	Florida Dept. of Business & Professional Regulation	Registration License accepted for Over-the Counter Drug Manufacturer, Cosmetic Manufacture, and Prescription Manufacturer

SECTION 5: ADDITIONAL INFORMATION

Hazard Plan (HACCP) / DATE IMPLEMENTED:	NA for topical products, micro tested as specified
STATISTICAL PROCESS CONTROL/PROCESS ANALYTICAL CONTROL:	NA
CORPORATE BIOTERRORISM ACT COMPLIANCE:	NA
DESCRIBE ALL MEASURES TAKEN BY FACILITY TO ENSURE PRODUCT QUALITY AND PRODUCT CONTAMINATION PREVENTION.	Designated
MEMBERSHIP IN INDUSTRY TRADE GROUPS:	NA

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?	NA for Topical
HOW DO YOU QUALIFY AN INGREDIENT MANUFACTURER?	SUPPLIER QUALIFICATION PROGRAM, QUESTIONNAIRE

SECTION 7: AUTHENTICITY OF INFORMATION & CONTACT INFORMATION

COMPANY NAME:	TROPICHEM RESEARCH LABS, LLC		
CONTACT NAME:	MIKE SMITH	TITLE:	VP SALES & MARKETING
E-MAIL ADDRESS:	MIKE.SMITH@TROPICHEM.COM		


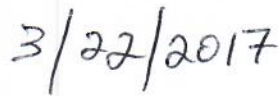
BY SIGNING BELOW, I CERTIFY THAT THE INFORMATION GIVEN BY ME TO THE NATIONAL ANIMAL SUPPLEMENT COUNCIL (NASC), INC. IS TRUE AND COMPLETE TO THE BEST OF MY KNOWLEDGE. I UNDERSTAND THAT IF THE INFORMATION PROVIDED IS NOT THOROUGH AND COMPLETE, NASC WILL REJECT THE FORM AND RESUBMISSION OF THE FORM WILL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



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SIGNATURE	DATE