K+S KALI GmbH, Postfach 10 20 29, 34111 Kassel

To whom it may concern

Contact:
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Ldf_GeneralQuestionnaire_EpsomSaltFCC_Version00_20140623.doc

Kassel, 25 June 2014

Dear Sir or Madam,

Thank you for the questionnaire which has been sent to us and your interest in our product

Epsom salt chemically pure, FCC

Due to the enormous number of such requests, individual questionnaires cannot longer been filled in by us.

According to our experience in the handling of questionnaires, you will find in the following pages all necessary information for the concerned product. If some of your questions have nevertheless not been considered in the following pages, please send them separately to us in order to enable us to send you a prompt answer. Please note this could result into a certain financial contribution according to the complexity of the request. More information on this, where applicable, can be given to you by your contact person.
Copies of documents like SOPs, validation reports or records are not distributed to customers. They can be examined during an on-site audit.

In the case that your own format needs to be updated, we will kindly ask you to consider the information in this questionnaire.

K+S KALI GmbH
Unit Health Care and Nutrition

Alexander Baart
Head of Unit

Dr. Laura De Francesco
Applied Research and Advisory Services

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Phone: +49 561 9301-1344
Chairman of the Supervisory Board: Norbert Steiner · Board of Management: Dr. Ralf Diekmann, Alexa Hergenröther, Steffen Kirchhof
Company seat: Kassel · Registered in Kassel (HRB 7452)

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A. General information					
		yes	no	n.a.	**Comment**
1	Company name and address				K+S KALI GmbH Bertha-von-Suttner-Str. 7 34131 Kassel, Germany Website: www.kali-gmbh.com
2	Primary contact				Please refer to your Sales contact person or your supplier in the case that you purchase our product via trader
3	General primary contact				Sales Health Care and Nutrition Phone: +49 561 9301 2025 Fax: +49 561 9301 1744 E-Mail: healthcarenutrition@kali-gmbh.com Technical Advisory Service Health Care and Nutrition Phone: +49 561 9301 2260 Mobile: +49 176 1234 8736 Fax: +49 561 9301 1416 E-Mail: healthcarenutrition@kali-gmbh.com
4	Manufacturing site address				K+S KALI GmbH Plant Werra, site Hattorf Hattorfer Strasse 36269 Philippsthal, Germany
5	Manufacturing site contact				Please refer first to the HQ or your direct sales contact person
6	Facility registration number				n/a
7	Foreign Establishment Identifier (U.S. FDA)				13864779130
8	Brief company history				Please refer to www.kali-gmbh.com
9	How long has the company been manufacturing the product?				Since 2003.
10	What other materials are manufactured at this site?				Magnesium sulphate in different grades: feed and pharma
11	Is the same material manufactured at other sites?		x		
12	Are any toxic, hazardous, or sensitizing materials manufactured in the same building or the same equipment?		x		
13	About what percentage of sales of this material is to pharmaceutical and or food manufacturers?				confidential
14	Is a list of your customer				confidential

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	available?				
15	Is the material/facility ISO certified?	x			Please refer to http://www.kali-gmbh.com/uken/healthcare_nutrition/products/bittersalz/bittersalzchemicallypure.html
16	Is there a certified HACCP system in place?		x		A not certified HACCP system is in place. Details are not forwarded
17	Is there a certification against a GFSI (Global Food Safety Initiative)-recognised scheme in place?		x		
B.	Organisation and personnel				
1	Approximately how many employees are in the K+S KALI GmbH company?				approx. 7900 employees
2	Approximately how many employees are at the production site in Hattorf?				approx. 70 employees (for the production/QC/QM) for the Epsom salt pilot plant
3	Are there written job descriptions describing the required qualifications and training needed?	x			
4	Is there an SOP for training, addressing both permanent and temporary employees?	x			
5	Are training and qualifications documented for each employee, including temporary employees?	x			
6	Are there initial and ongoing cGMP and/or ISO training and job-specific training (HACCP) for employees?	x			
7	Do employees have adequate training, experience, and qualifications for their responsibilities?	x			
8	Is there personal hygiene training for personnel handling product to help them understand necessary precautions to prevent contamination?	x			
9	Are employees with illness or open skin lesions that may contaminate or otherwise adversely affect the safety or quality of the product allowed to work in any operation that could cause contamination of the product?		x		

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10	Is there a jewelry policy in place?	x			
11	Are personnel required to wear clean and protective apparel where necessary to protect the product from contamination?	x			Different requirements with regard to the different production areas are applicable. Please note that clean areas are not applicable for us.
12	Are personnel observed to be in compliance with requirements for cleanliness, hair coverings, special clothing or protection in the various manufacturing, packaging, and testing areas?	x			
13	Is there a policy prohibiting storage and consumption of foods in production areas?	x			
14	Do the facility and its many departments (organizational units) operate in a state of control as defined by the GMP regulations?	x			
15	Does the facility/business unit operate under a facility or corporate quality policy?	x			
16	Is there an adequate program for handling complaints, including investigation to determine the causes, corrective actions, verification of the effectiveness of corrective actions, trend analyses and notification of appropriate parties including management?	x			
17	Is there an internal quality audit program that covers all areas of the operation to verify that SOPs and other procedures and policies are being followed, and to determine effectiveness of the quality systems?	x			
18	Based on the audit findings and recommendations, are steps taken to correct any areas of noncompliance?	x			
19	Are corrective actions documented? Is their effectiveness verified in subsequent audits?	x			
20	If any contractors (e.g.	x			

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	laboratories) are used, are they qualified and approved?				
C.	**Facilities**				
I.	**Buildings and Housekeeping**				
1	How old are the facilities?				The first building is dated 1970.
2	Is there adequate security to assure there is no entry by unauthorized persons?	x			
3	Are facilities of suitable size, design, and construction for the operations being performed?	x			
4	Are facilities maintained in a clean and orderly manner and in a good state of repair?	x			
5	Is there adequate lighting and, is it equipped with protection against shattering?	x			
6	Are all parts of the facility constructed in a way that makes them suitable for the manufacture, testing, and holding of pharmaceutical substances and to prevent contamination?	x			
7	If air is circulated to areas where product is exposed, is it filtered and controlled to eliminate dust cross-contamination? Are filters periodically checked and replaced and is this documented?	x			
8	If compressed air is used in cleaning or in processing, are they filtered to prevent contamination of product? Is there an established program for checking and replacing such filters?	x			
9	Are there clean, readily accessible toilet facilities that are maintained in good repair?	x			
10	Are hygiene trainings periodically performed?	x			
11	Is there an SOP for Pest Control?	x			Pest control is subcontracted
12	Are facilities properly maintained against rodents,	x			

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	birds, insects, and other vermin and are records kept? Are only approved rodenticides used?				
13	Is pest control performed by a licensed pest control contractor? Does the company provide a detailed written report of its activities and any rodenticides used?	x			
14	If there are open windows, are they adequately screened?	x			
15	If raw materials or intermediates are stored in silos, tanks, or other large containers, are the vents adequately protected to prevent entry of water, birds, and insects?			x	
II.	Warehouse/Receiving/Shipping				
1	Is the warehouse clean and well-organized, and can materials be easily located?	x			
2	Are shipping docks protected from weather where necessary?	x			
3	Are storage conditions for materials stored in the warehouse, to protect against deterioration and physical, chemical, or microbial contamination? Are they monitored?			x	For storage please refer to the recommended storage conditions on our Technical Data Sheet (TDS, http://www.kali-gmbh.com/uken/healthcare_nutrition/products/bittersalz/bittersalzchemicallypure.html)
4	Are materials requiring special storage conditions (e.g., refrigeration, freezing, low humidity) stored accordingly?		x		
5	Is there an SOP for receiving materials, including verification of material received vs. material ordered, quantity received, lot numbers, etc.?	x			
6	Is an identification code assigned to each lot of incoming raw materials to enable traceability?	x			
7	Are containers of incoming raw materials inspected upon receipt to ensure that their condition has not contaminated the material or	x			

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	caused deterioration?				
8	Is there an adequate system for designating and controlling quarantined and rejected materials?	x			
9	Are nonconforming materials clearly identified and segregated to prevent unintentional usage or sale?	x			
10	Are appropriate controls conducted to assure that unapproved product is not shipped to customers?	x			
11	Is there an SOP for handling returned goods, including proper identification, segregated storage, and QA involvement in evaluation and disposition?	x			
12	If materials are to be destroyed, are they tracked and controlled and destroyed in a timely fashion? Are records of such destruction maintained?	x			
D.	Equipment				
I.	Construction, Installation, Qualification				
1	Is there an SOP for qualifying new or significantly changed equipment?	x			
2	Is there a potential for contamination or cross-contamination from any source? If it is so, how is it controlled/prevented?		x		Production is done in a closed equipment system. Due to the raw materials origin, incoming inspection, installation of filters there is no risk of contamination.
3	If equipment is not dedicated, what other materials are manufactured in the same equipment?				Epsom salt is produced at the same pilot plant also in pharma and feed quality.
4	Is equipment of suitable type and size for intended use? Is it constructed so that product-contact surfaces are not reactive, additive, or absorptive and will not adversely affect the product?	x			
5	Have process parameters critical to quality been defined and have consequences been described regarding the effect on quality if critical parameters are exceeded?	x			Only CPs are defined. Consequences for CPs are described.

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6	Is reprocessing /recovery/reworking done?		x		
II.	Maintenance and calibration				
1	Is there a master list of all equipment that specifies those requiring maintenance and/or calibration?	x			List is not forwarded to customers.
2	Are there SOPs for inspection (monitoring the condition) and maintenance of equipment and of measuring and testing instruments? Do SOPs assign responsibilities including schedules?	x			
3	If equipment and instruments malfunction or are determined to be defective, are they immediately taken out of use?	x			
4	Are there SOPs for calibration of critical equipment, and measuring and testing instruments? Do SOPs assign responsibilities; including schedules?	x			
5	Are records maintained for maintenance and calibration operations?	x			
III.	Equipment cleaning				
1	Are there written procedures for cleaning, specifying cleaning agents and methods?	x			Water (potable and process) and product for cleaning the equipment are used.
2	Are there data to show that cleaning procedures for non-dedicated equipment are adequate to remove the previous materials? For active ingredients, have these procedures been validated?	x			
3	Is there an adequate system to assure that unclean equipment and utensils are not used?	x			
IV.	Computerised systems				
1	Are any computerised systems used in the manufacturing process and testing laboratories to perform food-related functions?	x			
2	Have such computerised systems been validated / verified (demonstrated to consistently function as expected)? Are reports	x			

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	available?				
3	Are suitable backup systems in place?	x			
4	Is there appropriate security to limit access to computerised systems, protect records from tampering, and prevent data alteration?	x			
5	If passwords are used as a security measure, are there provisions for periodic changing of passwords? Does a responsible person (e.g., system administrator) have a list of all passwords in case of emergency?	x	x		
E.	**Operations**				
I.	**General**				
1	Is your production on a continuous or batch basis? In an open or closed system?				Continuous basis, packaging is done batchwise. Closed system.
2	How is a batch defined?				Amount of product which is manufactured in a certain time (1 day). The typical amount of a batch is ca. 200-300 tons. batch numbering system according to the following principles is applied: 10-digit number: Number 1+2 = Product group; Number 3+4 = Year Number 5+6+7+8+9+10 = Sequential counter. The production date is printed uncoded.
3	Is there a potential for contamination or cross-contamination from any source? If so, how it is controlled / prevented?		x		Production is done in a closed equipment system. Due to the origin of the raw materials, incoming inspection, installation of filters (mesh size 5 x 5 mm) and etc. there is no risk of contamination.
4	Are there complete written master manufacturing instructions that specify formula, names and codes of raw materials, equipment, manufacturing flow, operating parameters, in-process sampling, packaging materials, labeling, and documentation of each significant step?	x			Master file is available. Please note that the document is not forwarded to customers.
5	Have process parameters critical to quality been defined and have consequences been described regarding the effect on quality if critical parameters are exceeded?	x			

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6	Are critical process parameters monitored and recorded?	x			
7	Has the current process been validated and is validation documented?	x			Validation reports are not forwarded to customers. Documents can be reviewed during on-site audit.
8	Are there written instructions describing how to use in-process data to control the process?	x			
II.	Packaging and labeling				
1	Is there documentation to support the use of the container/closure system, demonstrating that it is adequate to protect product from deterioration and contamination?	x			
2	Are tamper-evident seals used?	x			
3	Is the packaging material approved for food contact?	x			Packaging material fulfills the relevant requirements (e.g. Regulation (EC) No.1935/2004 and No. 2023/2006)
F.	Quality systems				
I.	Responsibilities and Authority				
1	Does a Quality Department exist as a separate organizational entity?	x			Quality Control and Quality Management are independent from production.
2	Does the QC unit routinely review production records to ensure that procedures were followed and properly documented?	x			
3	Does QC assure that manufacturing and testing records are reviewed before batches are released for sale?	x			
4	Are adequate laboratory space, equipment and qualified personnel available for required testing?	x			
5	Is there an adequate system, for reviewing and implementing compendial changes?	x			
6	Are there procedures in place for notifying responsible management in a timely manner of regulatory	x			

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	inspections, serious GMP deficiencies, product defects and related actions such as recalls and regulatory actions?				
7	Are the Quality organisation and responsibilities clearly defined in writing?	x			
8	Are all written procedures current and approved?	x			Document management system with audit trail in place.
9	Does the Quality Assurance (QA) unit alone have the authority and responsibility to approve or reject	x			
		x			Issues related to QA are ensured by QC and QM.
	- procedures and specifications?				Responsibilities and authorities for all processes are clearly defined.
	- process changes impacting on the identity, quality and purity of the material	x			Incoming control as visual check is done by the production staff.
	- raw materials and production batches	x			
	- packaging materials				Incoming control as visual check is done by the production staff.
	- in-process control (IPC)		x		IPC is done by the production staff, calibration of the equipment and review of the batch record is done by QC
	- new suppliers or subcontractors		x		Procedure is performed by QM after consultation with other responsible departments
II.	Change Control				
1	Is there an adequate system, described in an SOP, for controlling changes within the production process, including review and approval of changes to processes, documents, and equipment?	x			
2	Is QA involved in the change control process?	x			
3	Is a log maintained for changes to e.g. processes, materials, and methods?	x			
4	Has "significant process change" been defined for the product?	x			Part of our change control procedure.
5	Is there a system in place to	x			In case of major changes, which might influence the

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	assure that significant process changes and their effect on the product are communicated to the customer?				product quality, information is sent to our direct customers prior change implementation. Customer's approval is needed before delivery of such a modified product.
6	Is there a system to control changes to systems and programs that can have an effect on the quality of the product?	x			
7	Does the system assure that changes receive the proper review and approval with regard to potential effects before being instituted and that only authorized personnel can make such changes?	x			
8	Are personnel trained subsequent to changes?	x			
9	Is a log of system and program changes maintained?	x			
10	Is there an SOP or written policy that describes the records retention system that is in use?	x			
11	If a change is made, is the previous information still available?	x			Only as documentation
12	Is there a procedure concerning (electronic) signatures?	x			
13	Does it include a system to ensure that individuals are fully accountable and responsible for actions that are initiated under their (electronic) signatures?	x			
III.	Audit programs				
1	Is there an internal quality audit program that covers all areas of the operation to verify that SOPs and other procedures and policies are being followed, and to determine effectiveness of the quality systems?	x			
2	Based on the audit findings and recommendations, are steps taken to correct any areas of noncompliance? Are corrective actions documented? Is their effectiveness verified in	x			

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	subsequent audits?				
3	If any contractors (e.g., laboratories, packagers) are used, are they periodically audited and is their performance monitored?	x			
IV. Investigation of non-conformances					
1	Is there an SOP for investigation of manufacturing deviations and batch failures to determine the cause and institute corrective actions to prevent the situation from recurring?	x			
2	Is there an SOP for determining the disposition of in-process and final material that fails to meet specifications?	x			Downgrading or destruction.
3	Are records maintained of nonconforming materials, related investigations and corrective actions?	x			
4	Is there an SOP for investigation of out-of-specification (OOS) test results to assure that a uniform procedure is followed to determine why the OOS result occurred and that corrective actions are implemented?	x			
V. Raw material control					
1	Is a list of acceptable suppliers maintained?	x			
2	Are statistical sampling plans used to assure that the samples are representative of the lot?	x			Automatic sampling
3	Are there complete written instructions for testing and approving raw materials, including methods, equipment, operating parameters, acceptance specifications?	x			
4	Are raw materials approved before being used in production? Are appropriate controls exercised to assure that they are not used in a batch prior to release by Quality Control or responsible	x			

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	department?				
5	Are there chemical and microbial quality standards for process water, with an established monitoring program? If water is used in the process, is it at least potable water?	x			Potable water is used for the manufacturing of the product. Testing of the potable water is done quarterly according to the requirements of the German Drinking Water Ordinance.
VI. In-process testing					
1	Are there complete written instructions for testing and approving in-process materials, including methods, equipment, operating parameters, acceptance specifications?	x			
2	If operators perform in-process testing, have they been trained and was the training documented?	x			
3	Does QC periodically verify their results?	x			
VII. End-product control					
1	Is every batch sampled according to a plan that assures that the sample is representative of the batch?	x			
2	When and where is the finished product sampled for release?				Continuous automatic sampling out of the product stream before packaging.
3	Is every product batch tested and approved before shipment?	x			Please note that certain parameters are not checked batch wise. They are mentioned accordingly on the Certificate Of Analysis (CoA).
4	Are there complete written instructions for testing and releasing final product, including methods, equipment, operating parameters, and acceptance specifications?	x			
5	If the final product is compendial (e.g., FCC, Codex Alimentarius), are the tests and specifications compendial or are additional tests performed? List additional tests.				The product fulfills the requirements of the FCC, Codex Alimentarius (FAO/WHO). Please refer to TDS for more details. For the testing of the product, compendial or validated internal methods are used. Additional tests can be done if deemed necessary or if mutually agreed upon.
6	If skip lot testing is done, does the CoA clearly indicate which tests are performed on every lot and which are created via skip lot testing?	x			
7	Have specifications for particle	x			

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	size been established where appropriate?				
VIII.	Stability program				
1	What is known about the stability of this material?				The product is a stable inorganic substance.
2	Is an expiration date assigned to the material? If so, what is it?	x			A date of minimum durability of 5 years after production is applicable.
3	Are retention samples kept for every batch for at least one year past expiration date or, if no expiration date is assigned, according to a written policy?	x			Retention period of 6 years is applicable
IX.	Laboratories				
1	Do laboratories have adequate space and are they clean and orderly, with appropriate equipment for required tests?	x			
2	Are calibrated instruments labeled with date calibrated and date next calibration is due?	x			Where applicable.
3	Are calibration verifications performed on analytical balances using a range of weights (high, middle, low) based on the operating range of the balance?	x			Frequency of verification depends on the equipment.
4	Are appropriate reference standards used and are they stored in a proper manner to ensure stability? Are their expiration dates adequately monitored so they are not used beyond the expiration dates?	x			
5	Are reagents adequately controlled and monitored to assure that they are periodically replaced and that old reagents are not used?	x			
6	Are all containers of materials or solutions adequately labeled to determine identity, preparer, and dates of preparation and expiration (if applicable)?	x			
7	Are data and calculations checked by a second person and countersigned?	x			

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X. Product quality reviews					
1	Are periodic quality reviews conducted? Are they provided to, and reviewed by, quality and production management?	x			
2	Is the information in the periodic quality reviews evaluated with conclusions regarding need for revalidation? Are the evaluation and conclusion documented?	x			Documents are not forwarded.
G. Document Control					
I. Standard operating procedures (SOPs)					
1	Are there written SOPs for all areas of the operation? [note: This refers to SOPs other than manufacturing instructions or test methods.	x			
2	Is there an SOP for writing, handling, and updating SOPs? Are SOPs periodically reviewed and updated?	x			
3	Is a history of SOP revisions maintained?	x			
4	Are current SOPs readily available to employees?	x			
5	Is there an adequate system to assure that unneeded or obsolete documents are removed from use?	x			
II. Manufacturing, Packaging, and Testing Records					
1	Are batch / lot numbers assigned in such a manner that they are not duplicated and they enable tracing of all processes and batch records for each batch?	x			
2	If a new lot number is assigned to a reprocessed lot, can it be traced to the original batch?			x	No reprocessing.
3	Do shipping records allow traceability of specific lots to specific consignees and vice versa?	x			
4	Are there overwrites, white-outs, or pencil entries in official		x		

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	records?				
5	Are records legible? Are they appropriately signed and dated where required?	x			
6	Are batch and control records reviewed for completeness before filing?	x			
7	Is there an adequate system to track, control and maintain all records related to a batch?	x			
8	Are records retained for at least one year past the expiration date of the batch or, if no expiration date has been assigned, as specified in a records retention policy?	x			
III.	Microbiological testing				
1	Are there microbiological test results for every batch?				Testing on microbiology is not prescribed. Epsom salt promotes no microbiological growth.
H.	Further Information				
I.	Environmental Management System, Product responsibility and social commitment				
1	Does your company have a documented Environmental Management System? (EMS)	x			
2	Has your EMS been certified to ISO 14001:2004?		x		
3	Does your company have an environmental policy statement?	x			Please refer to http://www.k-plus-s.com/en/umwelt/
4	Please note that all relevant and important information on sustainability are available on http://www.k-plus-s.com/en/nachhaltigkeit/				

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Chairman of the Supervisory Board: Norbert Steiner · Board of Management: Dr. Ralf Diekmann, Alexa Hergenröther, Steffen Kirchhof
Company seat: Kassel · Registered in Kassel (HRB 7452)

A K+S Group Company