16218 Arthur Street Cerritos, CA 90703

Supplier Questionnaire

Instructions: Fill in all areas; please do not leave any blanks. Some questions may not be applicable (N/A), especially if the audit pertains to a distributor. Please make this indication.

Nature of audit	X Initial Assessment ☐ Re-qualification
Description of the business:	X Manufacturer (Complete Section A only) ☐ Distributor/ Broker (Complete Section B Only)

General Information

SECTION A: FOR MANUFACTURER		
To be completed by Manufacturer		
GENERAL INFORMATION		
1	Manufacturer Name	**RED B.V. ("RED Lecithin")**
2	Address	**Einsteinstraat 37, 3316 GG, Dordrecht, The Netherlands**
3	Mailing address if different than above	
4	Contact Person	**R.A.G. Blokvoord**
5	Phone number & E-mail address	**+1 818 730 1200 / blokvoord@redlecithin.com**
6	Fax number	**n.a.**
7	Web site	**www.redlecithin.com**
8	When was the manufacturing facility established?	**2017**
9	Total number of employees:	**10**
10	Number of shifts:	**1**
11	Provide an organizational chart, reflecting the reporting structure of the company.	X Yes* ☐ No *Attach a copy at the end of the document

Note: List the ingredients which are pertinent to the questionnaire on page 12

CAPTEK Softgel International
ENCAPSULATING QUALITY
16218 Arthur Street Cerritos, CA 90703

Regulatory Information

1	Provide the FDA Food Facility Registration Number(s) for the facility or facilities manufacturing this product.	FFRN: 11918892328
2	Registration Expiration Date	12/31/2024
3	Does the facility have a license from the state, county and/or city to operate the business as an ingredient manufacturer/supplier?	X Yes* ☐ No
	*If yes, are the registrations renewed every year or as required?	X Yes ☐ No
4	License No., Issuing federal/state agency and License description	**Dutch food authority (NVWA) does not issue reg numbers; they merely acknowledge our registration**
5	Has the facility been inspected by a government or regulatory agency?	X Yes* ☐ No
	*If yes, list name of agency and date of last inspection below for all that apply.	
	Agency Name: NVWA	Date of Last Audit: 02/21/2021 ☐ Certification/License X Other (Specify): **unannounced regular visit**
	Agency Name:	Date of Last Audit ☐ Certification/License ☐ Other (Specify):
	Agency Name:	Date of Last Audit ☐ Certification/License ☐ Other (Specify):
6	Are all regulatory inspections kept on file?	X Yes ☐ No
7	Do you have ISO certification?	☐ Yes Certification #_____ ☐ No *Provide a copy of the certificate* **FSSC22000 certified**
8	Is the facility FSMA Compliant	X Yes ☐ No ☐ N/A
9	Is there a HACCP (Hazard Analysis and Critical Control Point) program in-place?	X Yes* ☐ No
	*If yes, provide a copy of the manufacturer's HACCP or HARPC plan (as required by the FDA Food Safety Modernization Act, or FSMA). **Company policy to not share copies; can be witnessed during a site audit**	
10	Is HACCP or HARPC Training provided?	X Yes ☐ No
11	How often is HACCP or HARPC Training provided?	**Annually**
12	Do you have a written Food Defense Program in place?	X Yes ☐ No
	a. Does it include Food Defense Program Training?	X Yes ☐ No
	b. How often is the Food Defense Program Training provided?	**Annually**

13	Do you have a written Food Safety Plan in place?	X Yes ☐ No
	a. Does it include Food Safety Training?	**Yes**
	b. How often is the Food Safety Training provided?	**Annually**
14	Products manufactured/distributed	☐ Vitamins ☐ Minerals ☐ Amino acids ☐ Herbal Products ☐ Probiotics X Others **lecithin, lecithin-based compounds, and vegetable oils**
15	Is the material manufactured under cGMPs?	☐ Yes X No
16	Under which cGMPs is the material manufactured?	☐ Dietary Supplement (U.S. 21 CFR Part 111) ☐ Food (U.S. 21 CFR Part 117) ☐ Drug (U.S. 21 CFR Parts 210 & 211) ☐ Other:

Note: Information may be provided by the distributor/ broker, however all manufacturing information pertinent to the questionnaire is required.

Personnel

1	Are formal, documented job descriptions available for all company positions?	X Yes ☐ No
2	Do you have a written training program for all employees?	X Yes ☐ No
	a. Does it include cGMP training?	☐ Yes X No
	b. How often is cGMP training performed?	
3	Is a procedure in place for personnel health and hygiene that include appropriate garments, personal hygiene, hand washing, storage of personal items, and reporting illness?	X Yes ☐ No

Equipment, Facilities, and Utensils

1	Have IQ/OQ/PQ been performed for all major equipment/instruments?	X Yes ☐ No
2	Is there a written procedure for the cleaning and sanitization of all utensils and equipment?	X Yes ☐ No
3	Is there an SOP for facility general cleaning and sanitation	X Yes ☐ No
4	Is the facility or equipment used dedicated to each material?	☐ Yes X No*

	a. *If no, what is in place to prevent cross contamination?	**Segregation procedures, cleaning procedures, allergen monitoring/analyses, partially dedicated equipment, CIP of filling tank/pipes/equipment after each filling run, new packaging (no recycling)**
5	Is there a pest control program?	X Yes ☐ No
6	Are Restrooms and wash facilities kept clean and are not potential sources of Contamination? Are the cleaning records available for review upon request?	X Yes ☐ No
7	Is there a Preventive Maintenance (PM) program for all major equipment?	X Yes ☐ No
8	Are cleaning validation/verification performed on all major equipment?	X Yes ☐ No
9	Is measuring and test equipment inspected and calibrated prior to use?	X Yes ☐ No

Production and Process Control

1	Does the manufacturing/packaging facility have a written master manufacturing record in-place for each product code that details the production and process control systems for the product?	X Yes ☐ No
2	Does each manufacturing batch have a batch record that follows the master production record and is properly identified by product code number and lot number?	X Yes ☐ No
3	Is the manufacturing process validated/verified?	X Yes ☐ No ☐ NA
4	Is there a process flow diagram for the manufacture of the ingredient?	X Yes* ☐ No *Attach a copy at the end of the document
5	Are validations/verification reports reviewed and approved by the quality unit?	X Yes ☐ No*
	a. *If no, explain process.	
6	Do you have established Ingredient/Finished product specifications for components, in-process materials and finished products?	X Yes ☐ No
7	Is water required in the manufacturing process?	X Yes* ☐ No
8	*If yes, is there a purification system used & what type of system is used? **Potable water only**	
9	Is water tested?	X Yes* ☐ No

	*If yes, what is the frequency of the water testing?	**Twice Annually**
10	Do you have a supplier qualification procedure in-place which includes initial qualification, periodic verification/re-qualification and procedures for disqualification?	X Yes ☐ No
11	Are components used in manufacturing sampled, tested and the test results verified and approved by Quality Unity prior to use in production?	X Yes ☐ No
12	Are there separate areas for storage of Quarantined materials?	X Yes ☐ No
13	Does your facility handle substances which would be considered prohibited in sport (WADA prohibited list available at www.wada-ama.org)?	☐ Yes X No
14	Is your facility, to the best of its ability, able to supply raw materials that will not be contaminated with substances banned in sport?	X Yes ☐ No
15	Is there a written change control system in place for facility/equipment changes?	X Yes ☐ No
16	Are environmental controls (temperature, humidity) in-place and adequate in the facility?	X Yes ☐ No

Quality Control System

1	Does your company maintain a documented quality system?	X Yes ☐ No
2	Are their written procedures for the following activities? ***Provide a copy of SOP index***	
	Records of purchase orders:	X Yes ☐ No
	Issuance of documents & document control:	X Yes ☐ No
	Calibration of lab & manufacturing equipment:	X Yes ☐ No
	Standard operating procedures:	X Yes ☐ No
	Quality Control testing procedures:	X Yes ☐ No
	Data review & reporting process:	X Yes ☐ No
	Item identification & control:	X Yes ☐ No
3	Indicate the record retention policy (# of years) for the following listed below (NA if not applicable)	
	Manufacturing batch records:	Min. 5 years
	Lab records:	Min. 5 years
	Training records:	Min. 5 years
	Equipment validation/verification	Min. 5 years
	Calibration:	Min. 5 years
	Cleaning logs	Min. 5 years

	Distribution records	Min. 5 years
	Other	
4	Does your company have a Quality Unit?	X Yes ☐ No*
	Is the quality unit independent from the production department?	X Yes ☐ No*
	*If not, please explain:	
5	Are changes to documents reviewed and approved by the Quality unit?	X Yes ☐ No
	Is there a written procedure to ensure that only current documents are used?	X Yes ☐ No*
	*If not, please explain how they are maintained and by whom.	
6	Does the company have a documented internal cGMP audit program?	☐ Yes ** X No*
	** If yes, what is the frequency of the audits and who performs the internal audits?	
	*If no, please detail how adherence to cGMP's is evaluated: **We are FSSC 22000 (=GFSI); internal audits is a part of this**	
7	Describe your customer complaint handling program? **Procedure in place for customer complaints; reference P10-02**	
8	Is there a procedure to notify customers of a non-conformance resulting in product quality impact?	X Yes ☐ No
9	Are returned goods identified and controlled?	X Yes ☐ No
10	How will Captek Softgel be notified of corrective actions initiated as a result of a complaint submitted by Captek Softgel?	**In writing by the Quality Head**
11	Has a 3rd party auditing body evaluated the facility?	X Yes* ☐ No
	*If yes, indicate the agency and provide copies of certifications obtained (e.g. NSF, UL, NPA, MSC, Halal, Kosher, ISO)	**FSSC 22000, GMP+, Kosher, Halal, SKAL (Organic), SGS (Non-GMO IP)**
12	Are there procedures for final product inspection, sampling, and testing?	X Yes ☐ No
13	Is the final review of production documentation and product disposition performed by Quality Unit?	X Yes ☐ No

14	Is there an Allergen control program in-place	X Yes ☐ No
15	Are any residual solvents listed as class 1, 2, or 3 under USP <467> used in any part of your manufacturing?	X Yes* ☐ No
	*If yes, list the solvents used:	**Hexane; residual solvent levels well below the 290 ppm maximum concentration listed in Chapter 467**

Product Information

1	Provide a Safety Data Sheet (SDS).	X Attached
2	Provide Product Specification for supplied material.	X Attached
3	Provide an example Certificate of Analysis (COA).	X Attached
4	Country of Origin Statement	X Attached
5	Allergen Statement	X Attached
6	Kosher Certification	X Attached (if applicable) ☐ N/A
7	Halal Certification	x Attached (if applicable) ☐ N/A
8	Non-GMO	X Attached (if applicable) ☐ N/A
9	BSE/TSE Statement	X Attached (if applicable) ☐ N/A
10	Gluten certification	X Attached (if applicable) ☐ N/A
11	Organic Certification	X Attached (if applicable) ☐ N/A **We are Organic certified for our organic lecithins; product; does not apply for the product Captek is interested in**
12	Generally, Recognize as Safe (GRAS)	☐ Attached (if applicable) ☐ N/A **as per 21 CFR 184.1400 - Lecithin**
13	Is this material suitable for vegetarians?	X Yes ☐ No
14	Is this material suitable for vegans?	X Yes ☐ No

Quality Control Laboratories

1	Are there Quality Control laboratories located at the manufacturing site?	☐ Yes X No
2	Are analysis/ tests contracted out?	X Yes ☐ No
3	Are the contract laboratories qualified?	X Yes ☐ No
4	Are test methods verified/validated?	X Yes ☐ No
5	Is the review of all laboratory documents carried out by qualified Quality Control Personnel?	X Yes ☐ No
6	Are analytical standards purchased or qualified in-house?	☐ Qualified in-house* X Purchased
	*If qualified in-house, is there an SOP to qualify standards?	☐ Yes ☐ No

7	How frequently is the vendor or manufacturer analytical testing performed?	X Every Lot/Batch ☐ Skip Lot * ☐ Annual ☐ Other (Specify)_____
	* If skip lot, please explain the skip lot process.	
9	Are the Heavy Metals Specification on the CofA	☐ Yes X No **Heavy Metals are guaranteed as per TQSS, and are part of annual monitoring program; if desired, lower levels and batch-specific testing can be discussed and agreed. Batch-specific parameters are reported on COA**
Contaminants – Residual Solvent		
10	***This section must be completed only if an organic solvent is used in the manufacturing process.*** Residual solvent testing should be performed in accordance with current USP <467>. Note: Class 1 solvents are not permitted for use in Dietary Supplements**.** Materials found to contain Class 1 solvents will be rejected by Captek Softgel International.	
11	How frequently is this material tested for Residual Solvents?	☐ Every Lot/Batch ☐ Annual ☐ Skip Lot * ☐ N/A X Other (Specify)_____ **see statement attached**
	* If skip lot, please explain the skip lot process.	
12	Is this analysis performed by a contract laboratory, or by an internal QC laboratory?	☒ Contract Laboratory – Name: **Nofalab; TLR** ☐ Internal QC Laboratory
13	List the method used to test this product for Residual Solvents:	**ISO 9832**
14	Are retain samples maintained?	X Yes* ☐ No
	*If yes, for how long? **2 years min.**	
15	Is there a stability program? Is the product/expiration date supported by the stability study? Has stability of the products being provided to Captek been completed?	X Yes ☐ No X Yes ☐ No

16	Does a procedure (SOP) provide for segregation, identification, and documentation of discrepant material?	X Yes ☐ No
17	Does the Certificate of Analysis include manufacture/expiration date, test specifications, test method, and numerical or description test results? Is the Certificate of Analysis reviewed and approved by the Quality Unit?	X Yes ☐ No
18	Do you maintain records on the tractability of each botanical material? e.g., Country of origin, State, farm?	X Yes ☐ No ☐ N/A

Holding and Distributing

1	Are materials properly handled and stored to prevent damage/deterioration?	x Yes ☐ No
2	Are materials properly identified as to their contents?	X Yes ☐ No
3	Is there a SOP delineating steps to follow upon receipt of goods and responsibilities?	X Yes ☐ No
4	Is material adequately identified as to acceptance or rejection?	X Yes ☐ No
5	Is rejected material adequately controlled?	X Yes ☐ No
6	Is there a FEFO/FIFO system for materials?	X Yes ☐ No
7	Are materials supplied to Captek considered sensitive to environmental conditions?	X Yes* ☐ No
	*If yes, describe the storage and transportation requirements	**Store at temperatures between 15 and 35 degrees Celsius. Exposure to cold or frost should be avoided and may promote separation of the phospholipids from the oil; heat and remix the product to a homogenous state to avoid loss of functionality. Store in a clean, dry place, away from (excessive) sunlight. Shelf life is a minimum of 2 years after production date in the unopened original packaging**

Responsible Sourcing

This section must be completed for the Manufacturer of this material.

Is there a code of conduct available as to the rules of employment and workers' rights that is posted or available to all employees in their own language and understood by all?	X Yes ☐ No
Are employees aware of working conditions at hiring including working hours and terms of employment?	X Yes ☐ No
Are all workers or employees over the age of 15 or over the minimum working age established by the jurisdiction where the facility is located?	X Yes ☐ No
Is there a documented policy with regards to the minimum age of employees?	X Yes ☐ No
Are all employees paid at least the minimum wage established by the country, state, providence, or local government	X Yes ☐ No
Is there a non-discrimination policy in place? (It must account for nationality, age, gender, religion, and race of all employees)	X Yes ☐ No
Is there a policy against using corporal punishment, physical, mental, or verbal abuse, forced labor, debt bondage or slave labor?	X Yes ☐ No
Is there a documented overtime program that is communicated to all employees?	X Yes ☐ No
Are migrant workers or foreign contracted laborers used?	☐ Yes X No
Are personal identification documents such as passports or visas, retained by the employer or employment agency, if used?	X Yes ☐ No
If housing is provided, is it segregated by gender, and provides sufficient toilet and washing facilities to meet prevailing jurisdiction?	☐ Yes ☐ No **No houding provided**
Are all hazardous materials and chemicals disposed in a manner that is in accordance with local law?	X Yes ☐ No
Do facilities have a program in place to minimize pollution to the environment? Recycling is encouraged.	X Yes ☐ No
Are all emergency doors and exits in working conditions and unobstructed at all times?	X Yes ☐ No
Are workers required to wear personal protective equipment such as eye protection, hard hats, steel-	X Yes ☐ No

toed shoes, and other types of protective gear where danger may exist?	
Are uniforms or PPE, if required, provided at no cost to workers?	X Yes ☐ No
If this facility has been audited by a 3rd party responsible sourcing, social responsibility or Ethical sourcing organization indicate below the name of the organization /type of audits/standards and the dates of completion.	
Are you part of Sedex?	☐ Yes X No
Provide Sedex Company Reference	ZC #: ZS#:
Who is responsible for the social responsibilities policy and its implementation at your facility?	Name: **R.A.G. Blokvoord** Title: **Director** Email: **blokvoord@redlecithin.com**

List of ingredients

No.	Name	Manufacturer Name	Description/Comments
1	**REDLEC™ S Fluid 150 Premium**	**RED B.V.**	**High-end Sunflower Lecithin**
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SECTION B: FOR DISTRIBUTOR/BROKER		
To be completed by Distributor/Broker		
GENERAL INFORMATION		
1	Description of the business:	☐ Distributor ☐ Broker
2	Name of Distributor / Broker	
3	Address	
4	Mailing Address if Different than above.	
5	Please indicate the manufacturer name and address	
6	Products distributed: ☐ Vitamins ☐ Minerals ☐ Amino acids ☐ Herbal Products ☐ Probiotics ☐ Others _____(Specify)	
7	How long has the facility been established?	
8	Total number of employees:	
9	Approximate square footage of the facility:	
REGULATORY INFORMATION		

10	Is the facility FSMA Compliant?	☐ Yes ☐ No
11	Provide the FDA Food Facility Registration Number.	
12	Registration Expiration Date	
13	Do you meet the requirements of the FDA Rule for Foreign Supplier Verification Program (FSVP) for importers?	☐ Yes ☐ No
14	Name of FSVP Importer on Record	
15	Address	
16	Contact Person (Qualified Individual)	
17	Phone Number and Email	
18	Does the facility have a license from the state, county and/or city to operate the business as an ingredient manufacturer/supplier?	☐ Yes* ☐ No
	a. *If yes, are the registrations renewed every year or as required?	☐ Yes ☐ No
19	License No., Issuing federal/state agency and License description	
20	Has the facility been inspected by a government or regulatory agency?	☐ Yes* ☐ No
	a. *If yes, name of agency and date of last inspection.	
21	Are all regulatory inspections kept on file?	☐ Yes ☐ No
22	Is there a HACCP (Hazard Analysis and Critical Control Point) program in-place?	☐ Yes ☐ No
23	Is HACCP or HARPC Training provided?	☐ Yes ☐ No
24	How often is HACCP or HARPC Training provided?	
25	Do you have a written Food Defense Program in place?	☐ Yes ☐ No
26	Does it include Food Defense Program Training?	☐ Yes ☐ No
27	How often is the Food Defense Program Training provided?	
28	Do you have a written Food Safety Plan in place?	☐ Yes ☐ No
29	Does it include Food Safety Training?	☐ Yes ☐ No
30	How often is the Food Safety Training provided?	
31	Is there an executed Quality Agreement with all the manufacturers? ☐ Yes ☐ No	

32	Has the manufacturing facility been audited? ☐ Yes ☐ No If yes, please provide audit report. Audited by: Date of last audit inspection and outcome	
	PERSONNEL	
1	Are formal, documented job descriptions available for all company positions	☐ Yes ☐ No
2	Do you have a written training program for all employees?	☐ Yes ☐ No
3	Does it include cGMP training?	☐ Yes ☐ No
4	How often is cGMP training performed?	
	EQUIPMENT, FACILITIES, AND UTENSILS	
1	Is there an SOP for facility general cleaning?	☐ Yes ☐ No
2	Are Restrooms and wash facilities kept clean and are not potential sources of Contamination? Are the cleaning records available for review upon request?	☐ Yes ☐ No
	PRODUCTION AND PROCESS CONTROL	
1	Is there a written change control system is in place for facility/equipment changes?	☐ Yes ☐ No
2	Do you have a supplier qualification procedure in-place which includes initial qualification, periodic verification/re-qualification and procedures for disqualification?	☐ Yes ☐ No
3	If manufacturing process changed at manufacturing site, how are you notified? Please describe.	
4	If manufacturing process changed at manufacturing site, how would we be notified? Please describe.	
	QUALITY CONTROL SYSTEM	
1	Does your company maintain a documented quality system?	☐ Yes ☐ No

2	Indicate the record retention policy (# of years) for the following listed below. (NA if not applicable) Manufacturing batch records: _____years Lab records: _____years Training records: _____years Equipment validation/verification: _____years Calibration: _____years Distribution records: _____years Supplier Qualification Records: _____years Other(s), please specify: _____; _____years	
3	Is there a written recall SOP in place?	☐ Yes ☐ No
4	How is product recall handled?	
5	Describe your customer complaint handling program?	
6	How are returned goods identified and controlled? Please describe.	
7	Is there a Non-Conformance SOP in place?	☐ Yes ☐ No
	What is the procedure to notify customers of a non-conformance resulting in product quality impact?	
8	Describe your change control management system?	
	HOLDING AND DISTRIBUTING	
1	Are written procedures describing the receipt, identification, quarantine, sampling, examination and/or testing release, and handling of packaging and labelling materials?	☐ Yes ☐ No
2	How are materials properly handled and stored to prevent damage/deterioration? Please describe.	
3	How are materials identified (e.g. labels, bar code, color coding, etc.)?	
4	Please describe how receipt of goods are processed. How are responsibilities delineated?	

5	Is material adequately identified as to acceptance or rejection?	☐ Yes ☐ No
6	Is there a Rejected Material SOP in place?	☐ Yes ☐ No
	How are rejected material adequately controlled?	
7	Is there a FIFO/FEFO system for materials? ☐ Yes ☐ No	
8	Are there temperature & relative humidity controls in the facilities for the storage of all raw materials under the appropriate conditions?	☐ Yes ☐ No
9	Describe how temperature & relative humidity controls in the warehouse are maintained?	
10	Are materials supplied to Captek considered sensitive to environmental conditions?	☐ Yes ☐ No
11	If yes, are special transportation or storage conditions for the raw materials stated on the label.	☐ Yes ☐ No

Manufacturer completes section below. ☐ Not Applicable

All information that is provided in this survey is strictly **CONFIDENTIAL** and will be handled as **PROPRIETARY INFORMATION** solely for the use of Captek Softgel Int'l Inc.

By signing this survey, you agree that, if requested, Captek Softgel representative(s) will be allowed access to your facility for the purpose of verifying supplier compliance to your Self-Audit Survey.

I certify that all of the information in this survey is correct.

Company Name	**RED B.V.**
Title	**Director**
Email	**blokvoord@redlecithin.com**
Name (Printed)	**R.A.G. Blokvoord**
Signature (required)	
Date	01-23-2024

Distributor completes section below. ☐ Not Applicable

All information that is provided in this survey is strictly **CONFIDENTIAL** and will be handled as **PROPRIETARY INFORMATION** solely for the use of Captek Softgel Int'l Inc.

By signing this survey, you agree that, if requested, Captek Softgel representative(s) will be allowed access to your facility for the purpose of verifying supplier compliance to your Self-Audit Survey.

I certify that all of the information in this survey is correct.

Company Name	
Title	
Email	
Name (Printed)	
Signature (required)	
Date	

Below for CSI Use Only:

QA Review Name (Print)		☐ Approved ☐ Not Approved* ☐ Further Evaluation*
*Details/Comments:		
Signature:		Date

Questionnaire Answers