



# 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](mailto:b.bookout@nasc.cc) or mail to:

NASC  
 PO Box 5168  
 Sun City West, AZ 85376

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 X1)

SECTION 1: SITE OVERVIEW			
NAME AND ADDRESS OF COMPANY OR SITE RESPONSIBLE:	Golden Omega S.A. Av. Comandante San Martin 3460, Lote B2 Arica, Chile		
WEB SITE:	www.goldenomega.cl		
CONTACT PERSON	Jaime Ortega		
TELEPHONE NUMBER:	+562 24618800 / +56 582203000		
E-MAIL:	quality@goldenomega.cl		
<b>BUSINESS DESCRIPTION / SITE DETAILS:</b>			
<p>Golden Omega S.A., is a company dedicated to the development, manufacturing, sale and distribution of dietary ingredients, specially highly refined fish oil Omega-3 Acids concentrates from crude fish oil in different forms and presentations. Golden Omega's facility was designed and built from 2008 to 2011, starting operations in 2012. Its location in Arica is close to the best quality sources of crude fish oil in Chile and Peru.</p> <p>The design of the plant and processes was based on our own proprietary technology (patented) and provided technology from suppliers with vast experience in refining fish oil. The manufacturing standard follows the hygienic guidelines from ASME BPE and suggestions regarding equipment and facilities from the current Good Manufacturing Practices for pharmaceutical active ingredients ICHQ7. All the above resulted in a world class facility with closed and highly automated and controlled production systems. These conditions established the basement for a high-quality product, free from environmental pollutants and physical, chemical and microbiological contaminants.</p> <p>Our facility in Arica only transforms and refines fish oil, so it is free from allergen cross contamination and the product ingredients are not considered allergens according to the Food Allergen Labelling and Consumer Protection Act of 2004 (FALCPA).</p> <p>We manufacture our new line of solid ingredients at a qualified Contract Manufacturer in Europe. They follow very strict cleaning and testing procedures to avoid any contamination.</p> <p>Every component, ingredient and product are tested at our own quality control laboratory and released by our quality assurance unit. We are proudly certified by NSF in Good Manufacturing Practices for dietary supplements and dietary ingredients.</p>			
FACILITY SIZE / # EMPLOYEES:	120	DATE EST:	11/30/2020
GENERAL AND PRODUCT LIABILITY INSURANCE LEVELS:	Coverage: worldwide (excluding OFAC listed countries). Limit US\$ 15.000.000	UNION:	NA
SPECIFY TYPE(S) OF INGREDIENT(S), MANUFACTURING CAPABILITIES, PRODUCTS PRODUCED/SUPPLIED BY THE SITE, SERVICES AND THEIR INTENDED APPLICATIONS:	Supplied ingredients: highly refined fish oil Omega-3 Acids concentrates from crude fish oil in different forms and presentations. Dedicated own facility for the fish oil concentrates. Multipurpose qualified contract manufacturer facility for the solid products.		



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SITE ACTIVITIES CONDUCTED:	Arica: Crude fish oil storage and refining, Omega-3 concentrates transformation, distillation, and drumming. Storage of finished product. Germany: Continuous fluid bed granulation and drying of solid omega-3 concentrates complex. Packaging and storage of finished product.
ORGANIZATIONAL CHART:	<pre> graph TD     GD[General Director] --&gt; OD[Operations Director]     GD --&gt; ITD[Information Technology Director]     GD --&gt; AFD[Administration and Finance Director]     GD --&gt; CD[Commercial Director]     GD --&gt; RSD[Research and Development Director]     GD --&gt; QD[Quality Director]     OD --&gt; MM[Maintenance Manager]     OD --&gt; MAM[Materials Manager]     OD --&gt; PM[Production - Manager]     OD --&gt; HSEM[Health, Safety and Environmental Manager]     MAM --&gt; ProcM[Procurement Manager]     QD --&gt; QAM[Quality Assurance Manager]           </pre>

<b>SECTION 2: EVIDENCE OF COMPLIANCE</b>					
INDEPENDENT QUALITY CERTIFICATIONS:	<table border="1"> <tr> <td colspan="2" data-bbox="500 709 1554 793">           IF YES, SPECIFY:            SERNAPECSA (Chilean Sea Food Safety Agency), HACCP            NSF cGMP certification for dietary supplements and ingredients.         </td> </tr> <tr> <td data-bbox="500 793 1024 852">           QUALITY MANAGEMENT SYSTEM STANDARD:         </td> <td data-bbox="1024 793 1554 852">           NSF / ANSI 173, section 8         </td> </tr> </table>	IF YES, SPECIFY: SERNAPECSA (Chilean Sea Food Safety Agency), HACCP NSF cGMP certification for dietary supplements and ingredients.		QUALITY MANAGEMENT SYSTEM STANDARD:	NSF / ANSI 173, section 8
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	<p>APPROVAL CERTIFICATES:</p>	 
	<p>NUMBER AND NAME OF REGISTRAR WHO PROVIDED CERTIFICATE OF APPROVAL: <b>SERNAPESCA</b>  <b>NSF, National Science Foundation</b></p>	
<p>OTHER CERTIFICATIONS OR EXTERNAL AUDIT PROGRAMS:</p>	<p>FOS (Friends of the Sea)          Marine Trust, chain of custody (ex-IFFO RS CoC)          Dolphin Safe          Orivo, origin certification          HALAL</p>	
<p>WEB SITE:</p>	<p><a href="http://www.goldenomega.cl">www.goldenomega.cl</a></p>	
<p>DATE OF LAST FDA OR STATE AGENCY CGMP INSPECTION AND OUTCOME (PROVIDE COPY OF REPORT OF OBSERVATIONS FROM LAST FDA OR STATE INSPECTION):</p>	<p>Chilean agency (SERNAPESCA) October 2020          US FDA, February 2019 (Attached summary report)</p>	



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<b>SECTION 3: RAW MATERIAL SUPPLIERS &amp; CONTRACT MANUFACTURERS ONLY</b>	
DO YOU HAVE Q/C RELEASE REQUIREMENTS FOR ALL SHIPMENTS WHEN THEY ARRIVE: (YES / NO)	Yes
DO YOU SAMPLE EVERY LOT OF RAW MATERIALS RECEIVED: (YES / NO)	Yes
DO YOU RE-PACK LARGE QUANTITIES INTO SMALLER QUANTITIES AT YOUR FACILITY: (YES / NO)	No
DO YOU SAMPLE EVERY LOT: (YES / NO)	Yes
DO YOU PERFORM ANY BLENDING AT YOUR FACILITY (YES / NO)	Yes
<b>LIST ALL INGREDIENTS HELD AT YOUR FACILITY (ATTACH A LIST/DOCUMENT IF AVAILABLE: (YES / NO))</b>	
PHARMACEUTICAL:	No
NUTRITIONAL:	Yes
BOTANICAL:	No
MINERAL:	No
ENZYME:	Yes
HORMONE:	No
PROBIOTIC:	No
CHEMICAL (OTHER):	Yes
<b>METHODS CONDUCTED IN FACILITY: (YES / NO)</b>	
DO YOU USE AN IN-HOUSE LOT NUMBERING SYSTEM?	Yes
DO YOU EVER MIX MULTIPLE LOTS OF THE SAME INGREDIENT WHEN YOU BLEND?	Yes
<b>TESTING INFORMATION:</b>	
<b>*IF YOU RELY ON BOTH IN-HOUSE AND OUTSIDE CONTRACT LABS, PLEASE FILL OUT BOTH SECTIONS*</b>	
DOES THIS FACILITY RELY ON AN <b>IN-HOUSE</b> 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)	No
pH? (YES / NO)	No
MOISTURE? (YES / NO)	Yes
ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	No
HEAVY METALS? (YES / NO – IF YES SPECIFY)	Yes
OTHER? (YES / NO – IF YES SPECIFY)	Yes, Oil Oxidation and other oil tests.
<b>IF YOU HAVE AN IN-HOUSE LAB</b> PLEASE SPECIFY WHICH LAB ACCREDITATION ORGANIZATION(S) YOU ARE AFFILIATED WITH:	None, it is under the same cGMP certification from NSF



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<b>OUTSIDE CONTRACT LABS USED</b>	
PLEASE LIST YOUR MOST FREQUENTLY USED CONTRACT LABS AND THEIR ACCREDITATION STATUS: (e.g., ISO, FDA, USDA, AOAC, USP, NSF, NPA, A2LA, ANSI, ETC.) <b>*PLEASE PROVIDE ACCREDITATION NUMBER*</b>	
<b>NAME OF LAB #1:</b>	Eurofins GfA Lab Service GmbH
ADDRESS / LOCATION:	Neuländer Gewerbepark 4, 21079 Hamburg, Germany
CONTACT NAME / PHONE NUMBER:	Christian Drüppel, Analytical Service Manager +49 40 49 29 4 - 5053
LIST ANY CERTIFICATIONS FOR THE LAB:	ISO 17025, D-PL-14629-01-00 (Deutsche Akkreditierungsstelle)
<b>TESTING PERFORMED BY THE OUTSIDE LAB:</b>	
POTENCY ASSAY OF RAW MATERIALS? (YES / NO)	Yes
RAW MATERIAL ASSAY? (YES / NO)	No
MICROBIAL? (YES / NO – IF YES SPECIFY)	Yes
pH? (YES / NO)	No
MOISTURE? (YES / NO)	No
ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	Yes
HEAVY METALS? (YES / NO – IF YES SPECIFY)	Yes
OTHER? (YES / NO – IF YES SPECIFY)	PAH, Dioxins, MCPD and GE, Aldehyde profile, Radioactivity
<b>NAME OF LAB #2:</b>	CESMEC (Bureau Veritas Chile)
ADDRESS / LOCATION:	Ruta A-16, Km 10, Sitio 4544, Alto Hospicio, Chile
CONTACT NAME / PHONE NUMBER:	Blanca Lara Ogalde, Administradora de Contratos +56 572405000, Anexo 1000
LIST ANY CERTIFICATIONS FOR THE LAB:	ISO 17025, LE-826, (INN Chile)
<b>TESTING PERFORMED BY THE OUTSIDE LAB:</b>	
POTENCY ASSAY OF RAW MATERIALS? (YES / NO)	No
RAW MATERIAL ASSAY? (YES / NO)	No
MICROBIAL? (YES / NO – IF YES SPECIFY)	Yes, finished goods, surfaces and environment
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)	No



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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.

We follow the guidelines from 21CFR111 and 21CFR117.

Our quality system is built from five basic pillars Materials controls, Manufacturing Controls, Packaging controls, Laboratory controls, Facility and equipment controls. All of them are supported by risk analysis.

The following are the applicable chapters:

- Quality management
- CAPA system
- Supplier qualification
- Food safety
- Food defense
- Facilities
- Production and process controls
- Laboratory
- Warehouse and distribution
- Electronic signatures and records

IS FACILITY ISO CERTIFIED? YES / NO: IF YES SPECIFY THE ISO STANDARD AND ATTACH CURRENT CERTIFICATE.	No
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LIST AND ATTACH ANY OTHER CERTIFICATIONS OR EXTERNAL AUDIT PROGRAMS (E.G., NSF, USP, NPA, ISO, ETC.):	NSF, cGMP certification for dietary supplements and ingredients.
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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 13, 2019	US FDA	No FDA 483 Inspectional Observation was issued and there wer no discussion or suggestion items.
October 21, 2020	SERNAPESCA Chile	Approved facility, no observations.

**SECTION 5: ADDITIONAL INFORMATION**

Hazard Plan (HACCP) / DATE IMPLEMENTED:	June 2012, current version is from December 2018
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STATISTICAL PROCESS CONTROL/PROCESS ANALYTICAL CONTROL:	Based on product specifications and in process analytical control plan. Automatic process parameters recording and sampling and testing at predefined times for each process.
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CORPORATE BIOTERRORISM ACT COMPLIANCE:	FDA reg number 17548967934
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DESCRIBE ALL MEASURES TAKEN BY FACILITY TO ENSURE PRODUCT QUALITY AND PRODUCT CONTAMINATION PREVENTION.	All of them are described in our Quality Assurance and Product Safety Manual. It is available upon request. The design of the plant and processes was based on our own proprietary technology (patented) and provided technology from suppliers with vast experience in refining fish oil. The manufacturing standard follows the hygienic guidelines from ASME BPE and suggestions regarding equipment and facilities from the current Good Manufacturing Practices for pharmaceutical active ingredients ICHQ7. All the above resulted in a world class facility with closed and highly automated and controlled production systems. These conditions established the basement for a high-quality product, free from environmental pollutants and physical, chemical and microbiological contaminants. Our facility in Arica only transforms and refines fish oil, so it is free from allergen cross contamination and the product ingredients are not considered allergens
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	<p>according to the Food Allergen Labelling and Consumer Protection Act of 2004 (FALCPA). Every component, ingredient and product are tested according to their specifications at our own quality control laboratory and released by our quality assurance unit.</p>
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MEMBERSHIP IN INDUSTRY TRADE GROUPS:	GOED
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**SECTION 6: CONTRACT MANUFACTURERS NA**


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
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HOW DO YOU QUALIFY AN INGREDIENT MANUFACTURER?	NA
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**SECTION 7: AUTHENTICITY OF INFORMATION & CONTACT INFORMATION**

COMPANY NAME:	Golden Omega S.A.		
CONTACT NAME:	Jaime Ortega	TITLE:	Quality Director
E-MAIL ADDRESS:	<a href="mailto:quality@goldenomega.cl">quality@goldenomega.cl</a> , jaime.ortega@goldenomega.cl		

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.

	November 19, 2020
<b>SIGNATURE</b>	<b>DATE</b>