

OmegaPure™

Alaskan IFOS Five-Star Certified Fish Oil



OmegaPure 600 EC™ is available in 60 softgels & 120 softgels
OmegaPure 780 EC™ is available in 120 softgels
OmegaPure 820™ is available in 120 softgels
OmegaPure 900 EC™ is available in 90 softgels & 120 softgels

Discussion

IFOS Five-Star Certified Purity and quality are paramount when selecting fish oil supplements. This is precisely why XYMOGEN chose an Alaskan fish oil that is IFOS (international fish oil standards) five-star certified. IFOS is the only third-party testing and certification program for omega-3 fish oil products; it sets the gold standard for analyzing products for comparison to the highest industry standards with regard to contaminants, stability, heavy metals, and potency. Furthermore, IFOS provides detailed results for all testing categories for each individual lot tested. These assays are displayed on the IFOS website.^[1] IFOS is exclusively focused on omega-3 fish oil products, and it has long-standing experience with testing fish oil at all points along the supply chain. Five-star certification means:

- Product complies with all CRN[†]/GOED^{††}/WHO^{†††} testing categories
- Quantity of active ingredients matches the label claim
- Oxidation level is below the CRN/GOED standard by at least 75%
- PCB levels are below the CRN/GOED standard by at least 50%
- Dioxin levels are below the WHO standard by at least 50%

Source and Processing The omega-3 concentrate used in XYMOGEN's OmegaPure line of fish oils is exclusively sourced from US-caught fish, namely certified sustainable wild Alaskan walleye pollock and Pacific whiting obtained from the cold, clear waters off Alaska. Freshly caught fish are processed within hours to make quick-frozen fish fillets. The result is exceptionally fresh raw fish oil. To achieve the level of quality found in OmegaPure fish oils, a series of critical steps are undertaken: (1) raw fish oil triglycerides are broken down into ethyl esters; (2) EPA and DHA are separated from other fats and concentrated through flash distillation; (3) cold extraction further concentrates the oil, resulting in up to 85% omega-3; (4) molecular distillation removes fishy odor and taste, resulting in extremely fresh oil; (5) PCBs, chlorinated organopollutants, and toxic heavy metals are removed through filtration; and (6) high purity products are packaged in 190 kg drums or 900 kg totes under inert gas.

Clinical Applications

- » Affects the Production of Arachidonic Acid-Derived Eicosanoids*
- » Helps the Body Generate Specialized Proresolving Lipid Mediators, Such as Resolvins and Protectins*
- » Supports Cardiovascular Health*
- » Supports Healthy Mental Functioning*
- » Supports Healthy Glucose and Insulin Metabolism*

*OmegaPure Fish Oils are International Fish Oil Standards (IFOS) five-star certified, which assures the highest level of purity, stability, and potency in fish oils. Each dose of these concentrated fish oils provides 600-900 mg of EPA and DHA and is delivered in a small, fish-gelatin-based softgel. With the exception of OmegaPure 820, the softgels are covered with a GRAS-certified enteric coating so that they are easy to swallow and the EPA/DHA content is optimally absorbed. EPA and DHA from fish oil promote wellness by supporting cardiovascular health, cytokine balance, joint health, and brain and nervous system function.**

GRAS-Certified Enteric Coating OmegaPure fish oils employ a fish-gelatin—not a bovine-gelatin—softgel that is enteric-coated (except for OmegaPure 820) and GRAS-certified to further guarantee quality. The enteric coating helps ensure that the fish oils reach the small intestine before being metabolized, resulting in better delivery of actives to the intestines for absorption. This delivery may also reduce the occurrence of a fishy aftertaste.*

Ethyl Ester Form Despite aggressive marketing claims to the contrary, a recent publication by Oelrich et al found that no significant difference in the effect on serum triglycerides was detected in patients taking triglyceride (TG) or ethyl ester forms of omega-3 supplements.^[2] In the study, three fish oil supplementation forms were examined. The active therapy was 4 g/day of combined EPA and DHA provided as: a 90% TG formulation, a 60% TG formulation, or ethyl esters (i.e., 0% TG). In addition to the main finding, researchers also noted that the omega-3 fish oils provided in the ethyl ester form tended to have less impact on increasing LDL-cholesterol levels compared to the omega-3 fish oils delivered in the triglyceride form.*

Health Benefits of EPA/DHA Research and studies have shown that omega-3 fatty acids antagonize arachidonic acid-induced eicosanoid formation; help generate resolvins and protectins to aid the body's "cleanup" response to the arachidonic acid cascade; promote neurological health and mental functioning; and promote cardiovascular health, a balanced immune response, and healthy glucose and insulin metabolism.^[3-15] Research suggests that it takes 2 g/day of DHA supplementation over a period of a month to saturate the plasma and three to six months of supplementation to saturate the tissues.^[16] Concentrations of DHA increased in breast milk within less than a week of supplementation.*^[16]

[†] Council for Responsible Nutrition

^{††} Global Organization for EPA and DHA Omega-3

^{†††} World Health Organization

OmegaPure 600 EC™ Supplement Facts

Serving Size: 2 Softgels

	Amount Per Serving	%Daily Value
Calories	20	
Calories from Fat	20	
Total Fat	2 g	3%†
Fish Oil Concentrate	2 g	**
Total Omega-3 Fatty Acids	1.3 g	**
EPA (eicosapentaenoic acid)	720 mg	**
DHA (docosahexaenoic acid)	480 mg	**

† Percent Daily Value based on a 2,000 calorie diet.
 ** Daily Value not established.

Other Ingredients: Softgel (tilapia fish gelatin, vegetable glycerin, and purified water), GRAS enteric coating (purified water, ethylcellulose, sodium alginate, ammonium hydroxide, medium-chain triglycerides, oleic acid, and vegetable stearic acid), and mixed natural tocopherols.

Contains: Fish (Alaska pollock, Pacific whiting [sources of fish oil], tilapia [source of fish gelatin]) from certified sustainable sources.

DIRECTIONS: Take two softgels daily, or as directed by your healthcare practitioner.

Consult your healthcare practitioner prior to use. Individuals taking blood thinners or other medication should discuss potential interactions with their healthcare practitioner. Do not use if tamper seal is damaged.

DOES NOT CONTAIN: Wheat, gluten, corn, yeast, soy protein, dairy products, shellfish, peanuts, tree nuts, egg, ingredients derived from genetically modified organisms (GMOs), artificial colors, artificial sweeteners, or artificial preservatives.

STORAGE: Keep closed in a cool, dry place out of reach of children.



Third-Party Certificate of Analysis (COA) can be found by visiting:
<http://www.ifosprogram.com/consumer-reports.aspx>

OmegaPure 780 EC™ Supplement Facts

Serving Size: 2 Softgels

	Amount Per Serving	%Daily Value
Calories	20	
Calories from Fat	20	
Total Fat	2 g	3%†
Fish Oil Concentrate	2.8 g	**
Total Omega-3 Fatty Acids	1.82 g	**
EPA (eicosapentaenoic acid)	900 mg	**
DHA (docosahexaenoic acid)	660 mg	**

† Percent Daily Value based on a 2,000 calorie diet.
 ** Daily Value not established.

Other Ingredients: Softgel (tilapia fish gelatin, vegetable glycerin, and purified water), GRAS enteric coating (purified water, ethylcellulose, sodium alginate, ammonium hydroxide, medium-chain triglycerides, oleic acid, and vegetable stearic acid), and mixed natural tocopherols.

Contains: Fish (Alaska pollock, Pacific whiting [sources of fish oil], tilapia [source of fish gelatin]) from certified sustainable sources.

DIRECTIONS: Take one or two softgels one to three times daily, or as directed by your healthcare practitioner.

Consult your healthcare practitioner prior to use. Individuals taking blood thinners or other medication should discuss potential interactions with their healthcare practitioner. Do not use if tamper seal is damaged.

DOES NOT CONTAIN: Wheat, gluten, corn, yeast, soy protein, dairy products, shellfish, peanuts, tree nuts, egg, ingredients derived from genetically modified organisms (GMOs), artificial colors, artificial sweeteners, or artificial preservatives.

STORAGE: Keep tightly closed in a cool, dry place out of reach of children.



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OmegaPure 820™ Supplement Facts

Serving Size: 2 Softgels

	Amount Per Serving	%Daily Value
Calories	20	
Calories from Fat	20	
Total Fat	2 g	3%†
Fish Oil Concentrate	2.5 g	**
Total Omega-3 Fatty Acids	1.875 g	**
EPA (eicosapentaenoic acid)	1 g	**
DHA (docosahexaenoic acid)	640 mg	**

† Percent Daily Value based on a 2,000 calorie diet.
 ** Daily Value not established.

Other Ingredients: Softgel (tilapia fish gelatin, vegetable glycerin, and purified water), and mixed natural tocopherols

Contains: Fish (Alaska pollock, Pacific whiting [sources of fish oil], tilapia [source of fish gelatin]) from certified sustainable sources.

DIRECTIONS: Take one or two softgels one to three times daily, or as directed by your healthcare practitioner.

Consult your healthcare practitioner prior to use. Individuals taking blood thinners or other medication should discuss potential interactions with their healthcare practitioner. Do not use if tamper seal is damaged.

DOES NOT CONTAIN: Wheat, gluten, corn, yeast, soy protein, dairy products, shellfish, peanuts, tree nuts, egg, ingredients derived from genetically modified organisms (GMOs), artificial colors, artificial sweeteners, or artificial preservatives.

STORAGE: Keep tightly closed in a cool, dry place out of reach of children.



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OmegaPure 900 EC™ Supplement Facts

Serving Size: 1 Softgel

	Amount Per Serving	%Daily Value
Calories	10	
Calories from Fat	10	
Total Fat	1 g	2%†
Fish Oil Concentrate	1.29 g	**
Total Omega-3 Fatty Acids	967 mg	**
EPA (eicosapentaenoic acid)	515 mg	**
DHA (docosahexaenoic acid)	385 mg	*

† Percent Daily Value based on a 2,000 calorie diet.
 ** Daily Value not established.

Other Ingredients: Softgel (tilapia fish gelatin, vegetable glycerin, and purified water), GRAS enteric coating (ethylcellulose, sodium alginate, purified water, ammonium hydroxide, medium-chain triglycerides, oleic acid, and vegetable stearic acid), and mixed natural tocopherols.

Contains: Fish (Alaska pollock, Pacific whiting [sources of fish oil], tilapia [source of fish gelatin]) from certified sustainable sources.

DIRECTIONS: Take one softgel daily, or use as directed by your healthcare practitioner.

Consult your healthcare practitioner prior to use. Individuals taking blood thinners or other medication should discuss potential interactions with their healthcare practitioner. Do not use if tamper seal is damaged.

DOES NOT CONTAIN: Wheat, gluten, corn, yeast, soy protein, dairy products, shellfish, peanuts, tree nuts, egg, ingredients derived from genetically modified organisms (GMOs), artificial colors, artificial sweeteners, or artificial preservatives.

STORAGE: Keep tightly closed in a cool, dry place out of reach of children.



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*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

References

1. IFOS Consumer Reports. <http://www.ifosprogram.com/consumer-reports.aspx>. Accessed August 16, 2013.
2. Oelrich B, Dewell A, Gardner CD. Effect of fish oil supplementation on serum triglycerides, LDL cholesterol and LDL subfractions in hypertriglyceridemic adults. *Nutr Metab Cardiovasc Dis*. 2011 Sep 15. Epub ahead of print. [PMID: 21924882]
3. Storey A, McArdle F, Friedmann PS, et al. Eicosapentaenoic acid and docosahexaenoic acid reduce UVB- and TNF alpha-induced IL-8 secretion in keratinocytes and UVB-induced IL-8 in fibroblasts. *J Invest Dermatol*. 2005 Jan;124(1):248-55. [PMID: 15654981]
4. Kim YJ, Kim HJ, No JK, et al. Anti-inflammatory action of dietary fish oil and calorie restriction. *Life Sci*. 2006 Apr 18;78(21):2523-32. [PMID: 16438990]
5. Maroon JC, Bost JW. Omega-3 fatty acids (fish oil) as an anti-inflammatory: an alternative to nonsteroidal anti-inflammatory drugs for discogenic pain. *Surg Neurol*. 2006 Apr;65(4):326-31. [PMID: 16531187]
6. Weylandt KH, Chiu CY, Gomolka B, et al. Omega-3 fatty acids and their lipid mediators: towards an understanding of resolvin and protectin formation. *Prostaglandins Other Lipid Mediat*. 2012 Mar;97(3-4):73-82. [PMID: 22326554]
7. Kremmyda LS, Tvrzicka E, Stankova B, et al. Fatty acids as biocompounds: their role in human metabolism, health and disease: a review. part 2: fatty acid physiological roles and applications in human health and disease. *Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub*. 2011 Sep;155(3):195-218. [PMID: 22286806]
8. Frangou S, Lewis M, McCrone P. Efficacy of ethyl-eicosapentaenoic acid in bipolar depression: randomized double-blind placebo-controlled study. *Br J Psychiatry*. 2006 Jan;188:46-50. [PMID: 16388069]
9. Kankaanpaa P, Sutas Y, Salminen S, et al. Dietary fatty acids and allergy. *Ann Med*. 1999 Aug;31(4):282-87. [PMID: 10480759]
10. Ebbesson SO, Risica PM, Ebbesson LO, et al. Omega-3 fatty acids improve glucose tolerance and components of the metabolic syndrome in Alaskan Eskimos: the Alaska Siberia project. *Int J Circumpolar Health*. 2005 Sep;64(4):396-408. [PMID:16277123]
11. Nettleton JA, Katz R. n-3 long-chain polyunsaturated fatty acids in type 2 diabetes: a review. *J Am Diet Assoc*. 2005 Mar;105(3):428-40. [PMID:15746832]
12. Weitz D, Weintraub H, Fisher E, et al. Fish oil for the treatment of cardiovascular disease. *Cardiol Rev*. 2010 Sep-Oct;18(5):258-63. [PMID: 20699674]
13. Psota TL, Gebauer SK, Kris-Etherton P. Dietary omega-3 fatty acid intake and cardiovascular risk. *Am J Cardiol*. 2006 Aug 21;98(4A):3i-18i. [PMID: 16919512]
14. Sasaki J, Yokoyama M, Matsuzaki M, et al. Relationship between coronary artery disease and non-HDL-C, and effect of highly purified EPA on the risk of coronary artery disease in hypercholesterolemic patients treated with statins: sub-analysis of the Japan EPA Lipid Intervention Study (JELIS). *J Atheroscler Thromb*. 2012;19(2):194-204. [PMID: 22186099]
15. Zhang J, Wang C, Li L, et al. Inclusion of Atlantic salmon in the Chinese diet reduces cardiovascular disease risk markers in dyslipidemic adult men. *Nutr Res*. 2010 Jul;30(7):447-54. [PMID: 20797476]
16. Arterburn LM, Hall EB, Oken H. Distribution, interconversion, and dose response of n-3 fatty acids in humans. *Am J Clin Nutr*. 2006 Jun;83(Suppl):1467S-1476S. Review. [PMID: 16841856]

Additional references available upon request

All XYMOGEN® Formulas Meet or Exceed cGMP Quality Standards.

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