

Lonza DHA and VegaGels® – the entirely vegetarian solution

Lonza DHA is a pure vegetarian and allergen-free source of the important omega-3 fatty acid DHA (Docosahexaenoic acid), manufactured via a unique fermentation process from microalgae. Lonza DHA comes from renewable resources and is free of potential contaminants that are discussed for fish and seafood.

Soft capsules are one of the preferred solid dosage forms and widely used by pharmaceutical and nutritional industries. Consumer acceptance of soft capsules is high. VegaGels® from Swiss Caps contain only plant-derived ingredients and appeal to virtually all cultural groups. VegaGels® are solvent-free, free of genetically modified organisms, bear no risk regarding BSE/TSE and they fulfil the highest hygienic standards. VegaGels® can be obtained in Kosher and Halal certified qualities. The capsules themselves are single piece and therefore tamper proof.

VegaGels® containing Lonza DHA therefore are the ideal solution for an entirely vegetarian, most effective DHA supplement, suitable to everybody who wants to increase DHA intake.

DHA is the most important omega-3 fatty acid for human health, being particularly effective in the areas of brain, heart and eye health. It occurs naturally as a building block of cell membranes and contributes to membrane properties such as fluidity, flexibility and permeability. DHA in the body is mainly derived from intake of fish and seafood. However, it is well-known that dietary DHA intake with a typical western diet is well below recommended values.

It has become clear that dietary intake of the precursor omega-3 fatty acid, alpha-linolenic acid (ALA), which is available in a variety of plant oils, cannot make up for the low dietary intake of omega-3 DHA. Humans are very poor DHA synthesizers from precursor omega-3 fatty acids. Ageing, illness and stress, as well as excessive amounts of omega-6 rich oils (corn, safflower, sunflower, cotton seed) can all compromise conversion.

Various human studies which have addressed the question of bioconversion of ALA to EPA and DHA, have concluded that conversion of ALA to EPA is limited and conversion to DHA is extremely low (<0.1%).

Uptake of DHA from the diet may thus be critical for maintaining adequate membrane DHA concentrations. Health Organisations throughout the world have made specific recommendations to increase DHA levels.

In a recent study including more than 100 healthy vegetarians, eight weeks of Lonza DHA supplementation was found to significantly increase their DHA plasma levels as compared with placebo¹. Further, supplementation with

Lonza VegaGels®

Lonza DHA was found to decrease plasma triglyceride levels by 23%. This is good news since high circulating triglyceride levels in the plasma are associated with the severity and progression of atherosclerosis



and are recognized as independent risk factors for coronary heart disease.

However, DHA is not only beneficial for a healthy heart. As DHA is a major structural and functional building block of the **brain** many studies have shown beneficial effects in this area. DHA is required during foetal and child development for the growth and functional development of the brain. In adults, DHA maintains normal brain function, and scientific evidence links reduced DHA levels to mental and neurological health concerns.

The retina of the **eye** also is very rich in DHA, which explains that DHA plays a major role in visual function in both visual development in infants and visual function throughout life.

Lonza DHA production process

Using naturally occurring microalgae, Lonza's innovative technology allows DHA oils to be produced with a superior quality.

During the unique fermentation process, microalgae are grown in large quantities and accumulate significant quantities of DHA. After the fermentation process, Lonza DHA is extracted from the microalgae and refined in processes that are very similar to those used in the production of conventional vegetable oils.

What is Lonza DHA?

- Pure vegetarian source of omega-3 DHA
- Produced via a patented fermentation process from microalgae
- Allergen – solvent – GMO free
- Free of contaminations that are discussed for seafood
- Highly concentrated
- Superior sensory properties

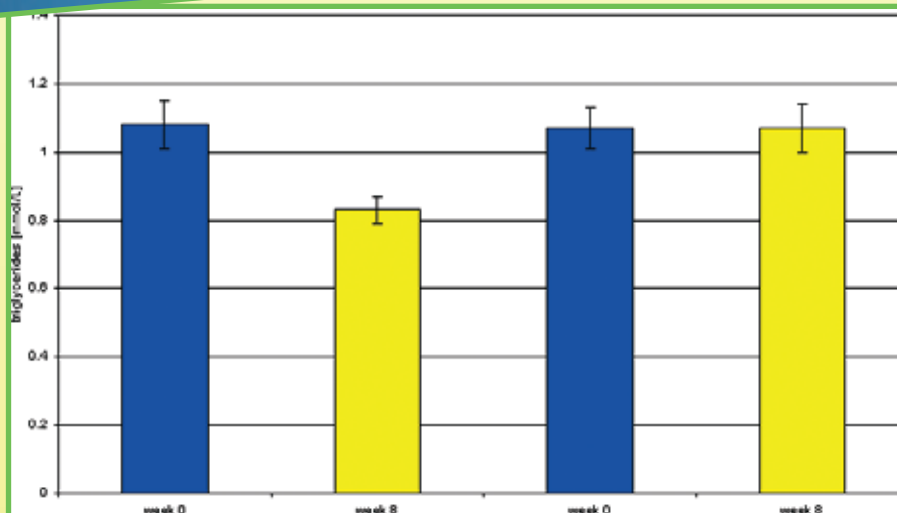


Figure 1: Decrease of triglycerides in plasma lipids after supplementation with Lonza DHA as compared to Placebo

Table 1: Stability of vegetarian DHA microalgal oil from Lonza in VegaGels®

Storage period	0 month	3 months	6 months	12 months	18 months	24 months
DHA* (% of TFA+)	43.5	43.7	43.2	43.7	43.0	43.3
Peroxide Value (POV)	3.1	3.5	5.0	2.6	3.9	3.9
Anisidin Value (AV)	12.7	14.4	16.9	15.7	17.9	18.1

Stability testing was done according to the ICH guidelines. Storage condition: 25°C / 60 %RH, packed in PVC/PVDC 250/40 blister. (*DHA = Docosahexaenoic acid; +TFA = total fatty acid)

The revolutionary patent-protected VegaGels® technology by Swiss Caps combines a newly designed extrusion process to produce a low-water content, gelatine-free ribbon and the most reliable and precise high-speed encapsulation technique based on the traditional "Rotary-Die process".

Preparation of fill material is done specific for each product right before the one-step encapsulation while the capsule shell-film formation is part of the VegaGels® encapsulation process. Together with restricted light and nitrogen protection it is therefore suitable for encapsulation of sensitive raw materials.

The main shell ingredient is starch. Starches used for VegaGels® are not known to cause allergic reactions. After testing a large variety of domestic and cultivated starches for VegaGels® Swiss Caps has chosen a chemical modified potato starch and a very specific quality of Tapioca starch that with its unique extrusion process can be transformed into nearly colourless, transparent thermoplastic starch (TPS) capsules. VegaGels® are completely neutral in taste and odour. They will please even the most sensitive consumer. The smooth and shiny surface builds up a slippery film in contact with saliva. VegaGels® are thus particularly easy to swallow, even without liquid. The capsule shape (either oval, oblong) is also ideal in this respect. VegaGels® are perfectly tolerated by the body. VegaGels® open in the stomach within the required disintegration time (Ph. Eur.) and break fully down within the digestive tract. No intolerances are to be expected.

Lonza DHA as a typical soft capsule product has been tested in VegaGels® according to ICH guidelines in various packaging containers and they show great stability. Improved stability of

actives has been documented in moisture protective packaging formats such as (PVC/PVDC or bottles) compared to simple PVC blisters and at lower temperature (25°C) compared to 40°C.

All ingredients used for the shell of VegaGels® are either food or approved food ingredients according to EC94/36 and EC95/2 and US food regulations. Ingredients used for VegaGels® based on Tapioca starch are additionally described in a pharmacopoeia. Thus the VegaGels® shell material is suitable for the pharmaceutical market.

As an option colorants can be added:

Many different colour tones, translucent or opaque are available to give your product a distinct look or enhance its attractiveness.

Shell composition/ingredients list: tapioca starch or chemical modified potato starch; humectants: sorbitol, maltitol, glycerol; emulsifier: glycerol monostearate; glazing agent: carnauba wax.

With global experience, Lonza's technical, research, sales and marketing staff are happy to work in partnership with customers and potential

VegaGels® from Swiss Caps

- First purely vegetarian soft capsule
- Multicultural acceptance
- Allergen-Solvent-GMO-BSE free
- Neutral in taste, easy to swallow
- Very tight shell (smell barrier, UV/O2 protection)
- No aftertaste
- Produced according to HACCP and GMP standards

customers to ensure the successful development and production of functional foods and nutraceuticals.

The Swiss Caps Group is one of the leading Full Service Manufacturer and Business Development Partners in the pharmaceutical and health-care industry – from development of modern solid dosage forms to production and packaging.

For further information, please come and see us at the HI Europe in Frankfurt.

1 Geppert J & Kraft V (2006). Microalgal docosahexaenoic acid decreases plasma triacylglycerol in normolipidaemic vegetarians: a randomised trial. *Br J Nutr* 95(4):779-786

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