

Carnipure™ Focus

Functional Foods and Beverages

Lonza

Introduction

As a food and beverage manufacturer, you are aware that consumers are increasingly searching for foods that offer a health benefit above and beyond their basic nutritional value, the so-called “functional foods and beverages”. You also know that in order to capitalize on this expanding market, the ingredients used in functional foods and beverages must be chosen with safety, efficacy and quality in mind.

The successful introduction of a functional food can also be enhanced when consumers already recognize the health-enhancing ingredient in the food and especially when the ingredient’s health-promoting benefits are easily understood. With the above in mind, Carnipure™ can be considered to be a winning ingredient, helping functional food manufacturers capitalize on a healthy, growing market.

What is Carnipure™?

Carnipure™ is high quality L-Carnitine manufactured by the Swiss life-science company Lonza. L-Carnitine is a nutrient that plays an important role in energy metabolism. The proprietary Carnipure™ production process was invented by Lonza scientists in Switzerland. It directly produces the L-isomer of Carnitine, the beneficial form found in nature. Products displaying the Carnipure™ quality seal on the packaging show the consumer that they contain pure L-Carnitine from Lonza.



Carnipure™ offers purest L-Carnitine and is a trademark of Lonza Ltd, Switzerland.

At Lonza, delivering safer, effective and the high quality ingredients is a responsibility we take very seriously. We have been supplying Carnipure™ crystalline and Carnipure™ tartrate to the dietary supplement, pharmaceutical and infant formula industries globally for years. Carnipure™ is a well established dietary supplement around the world, millions of consumers already know L-Carnitine and its health promoting benefits.

Rising consumer interest in health, growing awareness of the benefits of exercise and the perceived need to cope with increasingly busy lifestyles have combined to boost the demand for products specifically designed to aid performance, moving many products once seen as special nutrition lines out into the mainstream market. One of these products is Carnipure™.

Both Carnipure™ crystalline and Carnipure™ tartrate are (self-affirmed GRAS) Generally Recognized as Safe and thus also suitable for use in L-Carnitine enriched conventional foods and beverages. In the European Union, both products are approved



for the use in foods for particular nutritional uses (PARNUTS foods) according to the European Commission Directives 2001/15/EC and 2004/5/EC, respectively. There has been a positive safety evaluation by the European Food Safety Authority for up to 2 grams of L-Carnitine (equivalent to 3 grams of Carnipure™ tartrate) per day for use in PARNUTS foods.

Why Add Carnipure™ to Conventional Foods and Beverages?

L-Carnitine is already naturally present in some conventional foods, especially red meats and can be produced to a limited extent in the body. Despite this there remain several justifiable reasons for adding this nutrient to conventional foods and beverages as a dietary source of L-Carnitine.

Firstly, in an effort to promote health and reduce the risk for chronic diseases, the “Dietary Guidelines for Americans, 2005”, advises, among other recommendations, to limit the intake of saturated fat. Foods that have high levels of saturated fat include beef, lamb and pork – the same foods are among the best dietary sources of L-Carnitine (note that L-Carnitine is found in the lean portion of the meat, not the fat). Therefore, these guidelines, although well-founded, may put the general population at risk of a lowered dietary L-Carnitine intake. This is significant because dietary intake contributes to about 75% of the body’s L-Carnitine stores and maintaining these stores can be considered vital to optimal health and well-being. As opposed to relying on red meat consumption for their L-Carnitine intake, the American consumer can choose from an alternative, convenient and healthy food source of dietary L-Carnitine, in the form of Carnipure™ enriched conventional foods and beverages.

Secondly, although a vegetarian diet can be a healthy choice and has many benefits, there are certain nutritional risks associated with being a vegetarian. A vegetarian diet is invariably low in

dietary L-Carnitine as plant products are very poor sources of this nutrient. Furthermore, a vegetarian diet is frequently low in some of the nutrients that are essential for L-Carnitine biosynthesis in the body, such as lysine, methionine and iron. In the form of Carnipure™ enriched conventional foods and beverages, vegetarians may include L-Carnitine into their dietary choices and benefit from increased L-Carnitine intake.

Thirdly, in the USA and worldwide, there exists an increasingly strong demand for L-Carnitine as a dietary supplement. The addition of Carnipure™ to conventional foods and beverages provides health-conscious consumers with an alternative delivery form to the “energy nutrient”, L-Carnitine, as opposed to the traditional tablet and capsule products.

Carnipure™ is GRAS

In the United States, ingredients to be used in conventional foods and beverages must be either approved food additives or Generally Recognized as Safe (GRAS) among experts qualified by scientific training and experience. Both Carnipure™ crystalline and Carnipure™ tartrate are self-affirmed GRAS. The Expert Panel concluded that Carnipure™ crystalline and Carnipure™ tartrate may be safely added as a dietary source of L-Carnitine to the foods and beverages outlined in Table 1. The Expert Panel also gave recommendations as to the maximum level of L-Carnitine that can be used in these food products (Table 1).

| Food Category and Use | Use level for Carnipure™ (mg/RACC*) |
|---|-------------------------------------|
| Processed Fruits and Fruit Juices | |
| – fruit juices | 50 |
| – nectars | 50 |
| – fruit-flavored drinks | 50 |
| Beverages and Beverage Bases | |
| – energy beverages | 250 |
| – herbal teas | 250 |
| – carbonated soft drinks | 250 |
| Grain Products | |
| – health bars (breakfast, meal replacement, granola, energy bars) | 250 |
| Dairy Product Analogs | |
| – imitation milk | 250 |
| – soy milk | 250 |
| Plant Protein Products | |
| – meal replacement | 250 |
| – protein bars and supplements | 250 |

*RACC: Reference amounts customarily consumed per eating occasion

Table 1: Possible conventional food and beverage applications for Carnipure™ crystalline and Carnipure™ tartrate

Labeling Considerations for Conventional Foods and Beverages

When adding Carnipure™ to conventional foods and beverages it is possible to make two different types of claims on the product package, as outlined below.

| | |
|----------------------------------|--|
| Structure/function claims | These discuss the effect of a nutrient on the structure or function of the body, for example, “L-Carnitine assists in the breakdown of fat in cells to produce energy”, “L-Carnitine promotes cardiovascular health”, “L-Carnitine supports energy production”, or “L-Carnitine assists in fat breakdown in the body”. |
| Nutrient content claims | These discuss the quantity of a nutrient in a food or beverage, for example, “contains 250 mg L-Carnitine”. |



Carnipure™ crystalline and Carnipure™ tartrate: Product Specific Properties

| Carnipure™ crystalline | Carnipure™ tartrate |
|---|---|
| 100% pure L-Carnitine | Stable salt containing 68% L-Carnitine, 32% natural L-tartaric acid |
| White, crystalline powder | White, crystalline powder |
| Highly water soluble, forms colorless solutions | Highly water soluble, forms colorless solutions |
| Odorless | Odorless, pleasant fruity flavor |
| Heat stable | Heat stable |
| Hygroscopic – in higher dosages more suitable for liquid applications | Non-hygroscopic – suitable for all solid and liquid applications |
| (Self-affirmed GRAS) Generally Recognized as Safe | (Self-affirmed GRAS) Generally Recognized as Safe |
| Meets specifications of Food Chemicals Codex (F.C.C.) | L-Carnitine and L-tartaric acid used to produce Carnipure™ tartrate meet specifications of F.C.C. |
| | U.S. patent 5,073,376 and other international patents |
| OU-Kosher | OU-Kosher |
| Allergen free | Allergen free |
| Free from animal products and genetically modified organisms (GMOs) | Free from animal products and genetically modified organisms (GMOs) |
| Manufactured in compliance with cGMP | Manufactured in compliance with cGMP |

The physical properties of Carnipure™ crystalline and Carnipure™ tartrate make these products manufacturer friendly. As functional food ingredients, they can be used in any application where dietary enrichment is appropriate. Both products are bright white, heat stable, highly water soluble and form colorless solutions. Carnipure™ crystalline is inherently hygroscopic and therefore especially suited to liquid applications. Carnipure™ tartrate, on the other hand, is a non-hygroscopic salt of L-Carnitine and thus perfect to use in any solid or liquid application.

No interactions of both Carnipure™ crystalline and Carnipure™ tartrate with food components are known. Both substances are stable for 2 years or more if completely protected from humidity. Due to excellent handling properties and high stability under most processing conditions, Carnipure™ can be added to many different food product forms, including beverages, bars, cereals, biscuits, bread, dairy products and confectionery. Several tests have been made to study the stability of Carnipure™ during food processing. Baking trials with L-Carnitine have shown that this process has a negligible effect on L-Carnitine content, which allows addition of L-Carnitine during production processes operating at high temperatures.



Baking stability of Carnipure™ in wheat rolls and biscuits showed recovery rates of 98% (wheat rolls, baked for 5-10 minutes at 180°C) and 102% (biscuits, baked for 6-7 minutes at 200-250°C), respectively.

And so to conclude

The growing interest in Carnipure™ can be attributed to a number of factors including its basic function in helping convert fat into energy, its efficacy, its excellent safety profile and, of course, its suitability for processing. Carnipure™ has ideal physical properties and a pleasant taste and can directly be used as a value-added ingredient for new, healthy, functional foods and beverages.

Quality Science

While many of the health benefits of L-Carnitine are well established, by continuing to invest in quality science and clinical research, Lonza strives to uncover new potential applications, as well as improve upon our overall understanding of this exciting nutrient. We actively sponsor clinical research studies at universities throughout the world.

Quality Marketing

As the market leader in L-Carnitine, Lonza is conscious of the need to reach out and spread the "Carnipure™ word" to the US consumer. Our website www.carnipure.com is packed with useful information for customers and consumers alike. Lonza provides its customers with excellent marketing support.

Lonza – Your Provider in Functional Food and Beverage Development

With global experience, Lonza's technical, research, sales and marketing staff will assist customers to help promote the successful development and production of Carnipure™ enriched functional foods and beverages.

Note: This document is an overview of published scientific information on L-Carnitine and published scientific information on clinical and nutritional trials with L-Carnitine and its derivatives. No claims are made herein for any particular consumer product, nor can these statements be used on such consumer products. The recommended use for Carnipure™ is as a nutrient or dietary supplement. No warranty is made, either expressed or implied, regarding the information's accuracy or the results to be obtained from the use of such information and no warranty is expressed or implied concerning the use of these products. The buyer assumes all risks of use and/or handling.

The statements in this document have not been evaluated by any Food and Drug Administration. Lonza's Carnipure™ is not intended to diagnose, treat, cure or prevent any disease. References to regulatory approvals, permissions or status are general in nature only and do not relate to specific product applications. The regulatory status of the use of any Lonza ingredient in a product should be verified with reference to the specific finished product formulation in consultation with appropriate experts and/or regulatory agencies in that jurisdiction.

No statement is intended or should be construed as a recommendation to infringe any existing patent. The information contained herein is believed to be correct and corresponds to the latest state of scientific and technical knowledge.

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