

PRODUCT REGULATORY INFORMATION DATASHEET

Non-Botanical Dietary Ingredients

Section 1. PRODUCT INFORMATION	
PRODUCT NAME & CODE:	Carnipure® tartrate (Product code 1780.13)
COMMON OR USUAL NAME OF PRODUCT:	L-Carnitine L-tartrate
SCOPE OF DOCUMENT:	-
GENERAL PRODUCT INFORMATION:	Product information sheet attached

Section 2. MANUFACTURING INFORMATION	
NAME AND ADDRESS OF MANUFACTURING SITE:	Lonza Guangzhou Pharmaceutical Ltd, 68 Huangge Dadaobei, Nansha District, 511455 Guangzhou, China
MODE OF MANUFACTURING:	Chemical Synthesis
MANUFACTURING PROCESS:	Chemical Synthesis followed by downstream processing; flow chart attached
GMP COMPLIANCE:	Yes, in compliance with Food GMP; FSSC22000 certified
STERILIZATION OR FUMIGATION METHOD(S):	No
KNOWN OR POTENTIAL SOURCES OF IMPURITIES AND/OR CONTAMINANTS:	Contaminants and Residual solvents statements attached

Section 3. PHYSICAL/CHEMICAL INFORMATION				
INGREDIENT(S)				
COMMON OR USUAL NAME:	SYNONYM:	ORIGIN:	CAS NUMBER:	PERCENT:
L-Carnitine L-tartrate	-	Synthetic, China	36687-82-8	Assay: L-Carnitine: 67.2-69.2% (w/w) L-Tartaric Acid: 30.8-32.8% (w/w)
CURRENT PRODUCT SPECIFICATION SHEET ATTACHED:			Yes	
BIOASSAY METHOD:			Titration	
DOES THIS RAW MATERIAL COMPLY WITH THE CALIFORNIA PROPOSITION 65, ALSO KNOWN AS THE SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986?			Yes, see Safety Data Sheet (available on request)	

Section 4. LABELING INFORMATION	
REQUIRED FINISHED PRODUCT LABEL STATEMENTS:	-
RECOMMENDED RESTRICTIONS OF USE:	-
NUTRITIONAL/SUPPLEMENT FACTS LABELING:	Nutritional information attached
OTHER:	-

Section 5. REGULATORY INFORMATION	
PATENT COVERAGE:	-
COMPENDIAL GRADE:	FCC
REGULATORY STATUS AND SUPPORTING DOCUMENTS:	Self-affirmed GRAS status DSHEA "Grandfathered" status
PRODUCT MASTER FILE(S):	-
BSE/TSE INFORMATION:	Non-animal origin; statement attached
VEGAN OR VEGETARIAN STATUS:	Suitable for vegetarians and vegans
ALLERGENS/ HYPERSENSITIVITES:	No; statement attached
PRESERVATIVES (or PROCESSING AIDS):	-
KOSHER/HALAL/ORGANIC STATUS*:	Kosher (Orthodox Union) Halal (MUI)
GM STATUS (for each dietary ingredient):	Non GMO; statement attached
TARIFF CODE FOR IMPORT/EXPORT:	On request only; please specify country
FDA REGISTRATION NUMBER	Available on request

*Include certifying agency/authority

Section 6. MISCELLANEOUS PRODUCT INFORMATION	
BATCH/LOT NUMBERING SYSTEM:	Bnnnyy: B = Carnipure® tartrate nnn = consecutive number in a year yy = year of production
BATCH DEFINITION:	One production run
EXPIRATION DATING:	24 months from date of production (retests date)
RECOMMENDED STORAGE CONDITIONS:	Dry place, 5-25°C
OTHER OPTIONAL INFORMATION:	
PACKAGE SIZE(S):	25 kg net
RECYCLED PACKAGING MATERIALS:	-
SUGGESTED PRODUCT CLAIMS, SUPPORTING DOCUMENTATION INCLUDED:	-
MSDS ATTACHED:	Available on request
OTHER PRODUCT SAFETY INFORMATION:	-

Section 7. REVISIONS			
REVISION DATE:	30 March 2021	REVISION LEVEL:	Regulatory Affairs

Section 8. CONTACT INFORMATION			
COMPANY NAME:	Lonza Ltd		
CONTACT NAME:	Richard Sasse	TITLE:	Product Manager Carnipure®
CONTACT PHONE:	+31 76 548 0018	EMAIL:	Richard.Sasse@lonza.com

Product specification

Carnipure® tartrate

PRODUCT SPECIFICATION

NAME :	Carnipure® tartrate
TRADE NAME :	Carnipure® tartrate
GENERIC NAME :	L-carnitine L-tartrate
PRODUCT CODE :	1780.13

Packing

25kg net in double polyethylene bag in external drum, including silica bags in between the PE bags

Storage

In dry place, 5-25 °C

Retest date

2 years from date of production

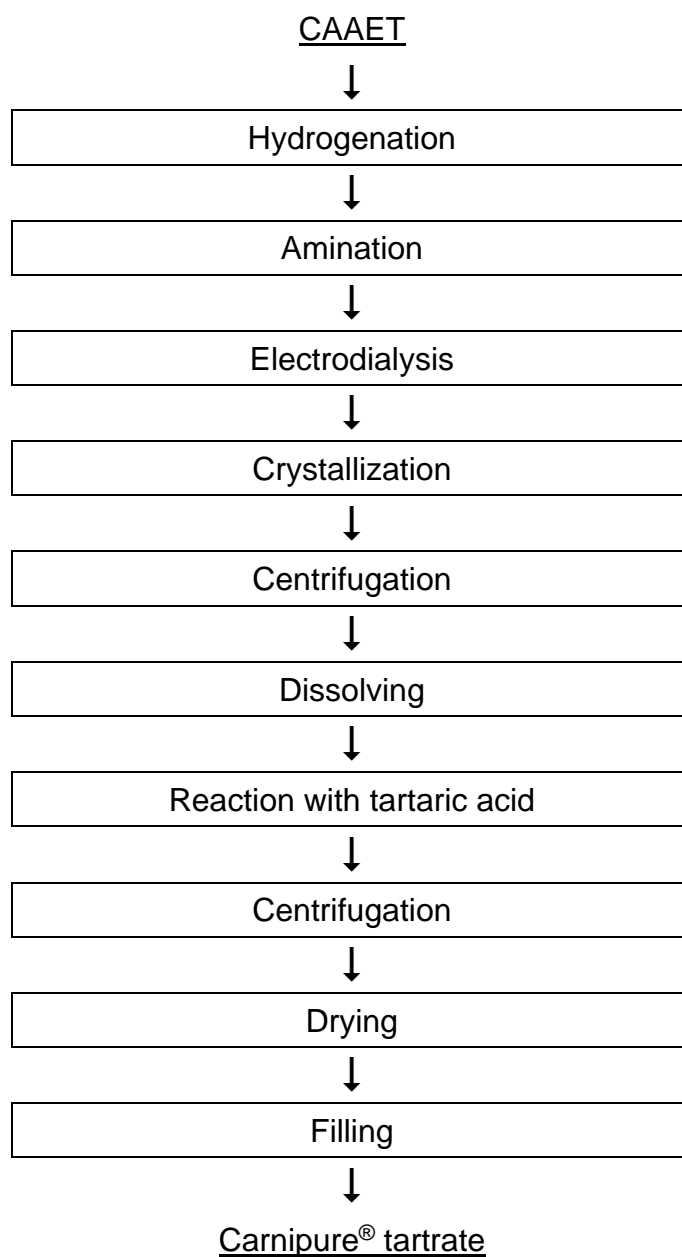
Documentation

FSSC22000, food grade

SPECIFICATIONS

PARAMETER	LIMITS	C of A
Appearance	Crystalline Powder	+
Colour	White	+
Identity (IR)	Corresponds	+
Assay of L-Carnitine (titration)	67.2 - 69.2 %w/w	+
Assay of L-tartaric acid (titration)	30.8 - 32.8 %w/w	+
Spec. rotation (Na-D, 20°C, c=10 in water)	-11.0 - -9.5 °	+
Water (KF)	max. 0.50 %w/w	+
Heavy metals (as Pb, limit test)	max. 10 mg/kg	+
Sulfated ash (2h, 600°C)	max. 0.10 %w/w	+
pH (2.5g/50ml water)	3.0 - 4.5	+
Total aerobic microbial count (USP/EP)	max. 50 CFU/g	+

Production of Carnipure® tartrate Product code 1780.13



The information contained herein corresponds to Lonza's knowledge on the subject at the date of publication and is, to the best of our knowledge, accurate. However, Lonza refuses any liability for the application and use of further processed material containing our products. Solely the manufacturer of the final product is responsible according to the relevant regulations.

Nutritional Information

Carnipure® tartrate (Prod. code 1780.13)

Typical values* based on 100 g

Energy	96 416	kcal kJ
Fat	0	g
- thereof saturated fatty acids	0	g
Carbohydrates	0	g
- thereof sugars	0	g
Protein (Non Protein Nitrogen)	0 (5.9)	g (g)
Salt (as sodium)	≤ 0.1	g

*Except for sodium, the values are calculated values.

The energy content is calculated based on 32 gram organic acid equivalents per 100 gram from the tartrate, with an average energy content of 3 kcal/g or 13 kJ for organic acids (Codex Alimentarius, Guidelines on nutrition labelling 1985, revised 2013).

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Statement on Contaminants

We hereby confirm that

Carnipure® tartrate
(Product code 1780.13)
Food Grade

manufactured by Lonza in Guangzhou Nansha (China) is produced by chemical synthesis.

Based on the process and raw materials used for production, contaminants listed in *Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs* as well as *Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin*, and respective amendments, are not expected to be present in the product.

Carnipure® tartrate is periodically tested for the following contaminants:

- Mycotoxins (Aflatoxins B1, B2, G1, G2)
- Metals (Lead, Cadmium, Mercury, Methylmercury, Arsenic)
- Mineral Oil (MOSH, POSH, MOAH)
- Dioxins and Furans
- Polychlorinated Biphenyls (PCBs)
- Polycyclic Aromatic Hydrocarbons (PAHs)
- Pesticides
- Chlorate and Perchlorate
- Melamine
- Quarternary Ammonium Compounds

In 2020, the results of the tests, performed by an accredited 3rd party lab according to defined test methods, showed that the respective contaminants (for Dioxins, Furans and PCB refers to WHO (2005) Lower-bound values) were below indicated quantification or detection levels.

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Statement on Residual Solvents

We hereby confirm that

Carnipure® tartrate
(Product code 1780.13)
Food Grade

manufactured by Lonza in Guangzhou Nansha (China) is produced with the use of crystallization solvents in line with the ICH Q3C (R6) Residual solvents guideline.

The residue levels of these solvents are specified as follows:

Name of the solvent	Guideline class	Concentration limit guideline	Lonza specification	Complies with guideline
Ethanol	Class 3	5000 ppm	0.5% w/w	yes
Acetone	Class 3	5000 ppm	0.1% w/w	yes

Carnipure® tartrate complies with EU Directive 2009/32/EC on extraction solvents used in the production of foodstuffs and food ingredients.

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Statement on BSE/TSE

We hereby confirm that

Carnipure® tartrate
(Product code 1780.13)
Food Grade

manufactured by Lonza in Guangzhou Nansha (China) is produced by chemical synthesis.

No products of animal origin are used in the production of Carnipure® tartrate.

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Regulatory Affairs Nutrition Ingredients / UF
regulatorynutrition@lonza.com

30 March 2021
max validity 2 years

Statement on Vegetarian/Vegan Suitability

We hereby confirm that

**Carnipure® tartrate
(Product code 1780.13)**

manufactured by Lonza in Guangzhou Nansha (China) is of synthetic origin. No products of animal origin are used in the production process.

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Regulatory Affairs Nutrition Ingredients / UF
regulatorynutrition@lonza.com

14 April 2021
max validity 2 years

Statement on Genetically Modified Organisms (GMOs) and Bioengineered Genetic Materials

We hereby confirm that

Carnipure® tartrate
(Product code 1780.13)
Food Grade

manufactured by Lonza in Guangzhou Nansha (China) is neither produced from nor does it contain any GMOs or bioengineered genetic materials.

EU Compliance:

Carnipure® tartrate does not need labelling according to the following regulations

- Directive 2001/18/EC on the deliberate release of GMOs into the environment
- Regulation (EC) 1829/2003 on genetically modified food and feed
- Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory
- Regulation (EC) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms
- Directive 2009/41/EC on contained use of genetically modified micro-organisms.
- Regulation (EC) 1946/2003 on transboundary movements of GMOs

US Compliance:

Carnipure® tartrate is not a bioengineered food and is not derived from or contain bioengineered substances according to the National Bioengineered Food Disclosure Standard at 7 CFR Part 66.

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Carnipure® tartrate: Information on Allergens (1/2)

Allergenic substances as listed in <ul style="list-style-type: none"> • Codex Alimentarius: Codex General Standard for the Labelling of Prepacked Foods • Regulation (EU) No 1169/2011 on the provision of food information to consumers • Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4) 	Natural occurrence or used during production *	Possibility of cross contamination due to presence in the same facility/on the same line *
Cereals containing gluten, namely wheat (triticum), rye, barley, oats, spelt, kamut or their hybridized strains and products thereof	No	No
Crustaceans and products thereof	No	No
Eggs and products thereof	No	No
Fish and products thereof	No	No
Peanuts and products thereof	No	No
Soybeans and products thereof	No	No
Milk and products thereof (including lactose)	No	No
(Tree)nuts, namely Almond (<i>Prunus dulcis</i>), Beech nut (<i>Fagus</i> spp.), Brazil nut (<i>Bertholletia excelsa</i>), Cashew (<i>Anacardium occidentale</i>), Chestnut (Chinese, American, European, Seguin) (<i>Castanea</i> spp.), Chinquapin (<i>Castanea pumila</i>), Coconut (<i>Cocos nucifera</i> L.), Ginkgo nut (<i>Ginkgo biloba</i> L.), Hazelnut/Filbert (<i>Corylus</i> spp.), Hickory nut (<i>Carya</i> spp.), Lichee nut (<i>Litchi chinensis</i> Sonn.), Macadamia /Bushnut or Queensland nut (<i>Macadamia</i> spp.), Pecan (<i>Carya illinoensis</i>), Pine nut/Pinon nut (<i>Pinus</i> spp.), Pili nut (<i>Canarium ovatum</i>), Pistachio (<i>Pistacia vera</i> L.), Sheanut (<i>Vitellaria paradoxa</i>), Walnut (English, Persian, Black, Japanese, California, Heartnut, Butternut) (<i>Juglans</i> spp.) and products thereof	No	No
Celery and products thereof	No	No
Mustard and product thereof	No	No
Sesame seeds and products thereof	No	No
Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO ₂	No	No
Lupins and products thereof	No	No
Molluscs and products thereof	No	No

* Please note the above information relates to the natural presence or absence of allergens. Absence of allergens has not been confirmed by testing.

Carnipure® tartrate: Information on Allergens (2/2)

Other substances potentially regarded as allergenic or causing intolerances	Natural occurrence or used during production *	Possibility of cross contamination due to presence in the same facility/on the same line *
Apple	No	No
Artificial sweeteners incl aspartame, saccharin	No	No
Banana	No	No
Bee pollen	No	No
Beef	No	No
Buckwheat	No	No
Carrot	No	No
Chicken	No	No
Cocoa	No	No
Coriander	No	No
Corn/maize	No	No
Cotton seeds	No	No
Flavourings	No	No
Food colourings incl tartrazine	No	No
Galactose	No	No
Gelatin	No	No
Glutamic acid (E620) and Glutamates (E621-E625)	No	No
Kiwifruit	No	No
Latex	No	No
Legumes	No	No
Mango	No	No
Mushrooms	No	No
Orange	No	No
Peach	No	No
Poppy seeds	No	No
Pork	No	No
Preservatives incl benzoates, sorbic acid	No	No
Propolis	No	No
Royal jelly	No	No
Sugar alcohols incl erythritol, isomalt, lactitol, maltitol, mannitol, polydextrose, sorbitol, xylitol	No	No
Tomato	No	No
Yam	No	No
Yeast	No	No

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