

# Product Technical Data Sheet AC code: AC02048f Product name: L-Carnitine L-Tartrate

1.Technical Data Sheet	
Chemical Name	(R) -BIS [(3-hydroxy-2-hydroxypropyl) trimethylamino ]-L tartrate
CAS number	36687-82-8
Molecular Weight	472.49
Molecular Formula	C18H36N2O12
Compliance (Food / Pharmacopoeia / FCC / Feed)	Food Grade
Source (animal, plant, mineral, petrochemical)	Synthetic

#### **Brief introduction:**

L-Carnitine is important for heart and brain function, muscle movement, and many other body processes. The body can convert L-carnitine to other chemicals called acetyl-L-carnitine and propionyl-L-carnitine. L-carnitine is used to increase L-carnitine levels in people whose natural level of L-carnitine is too low. Some people also use L-carnitine for conditions of the heart and blood vessels, serious kidney disease, and many other conditions, but there is no good scientific evidence to support these uses

 $L-Carnitine\ Tartrate\ is\ in\ white\ or\ almost\ white\ powder,\ with\ L-Tartaric\ acid\ content\ 31.8\%\pm1.0\%\ and\ levocarnitine\ assay\ 68.2\pm1.0\%$ 

Item	Standard	Analysis Method			
Appearance & Solubility					
Appearance The product is white crystal or crystalline powder					
Typical Analysis					
Identification	Consistent with the standard spectrum	IR			
L-Carnitine	67.5 ~ 69.2%	Titration			
Tartaric Acid	30.8 ~ 32.8%	Titration			
Loss on Drying	≤ 0.5%	USP43			
PH	3.0 ~ 4.5	USP43			
Specific Rotation	-11.0° ~-9.5°	USP43			
Residue on Ignition	≤0.5%	USP43			
Chlorine	≤0.4%	USP43			
Solvent of Residue	≤5000ppm	USP43			
Cyanide	Negative	CP2020			
Heavy metals					
Total Heavy Metals	≤10 ppm	USP 43 <231>			
Lead	≤0.5 ppm	USP 43 <251>			
Arsenic	≤1.0 ppm	USP 43 <211>			



Cadmium	≤1.0 ppm AAS					
Mercury	≤0.1 ppm	USP 43 <261>				
Microorganism						
Total Plate Count	≤1,000 cfu/g	USP 43 <61>				
Total Molds & Yeasts	≤100 cfu/g	USP 43 <61>				
E.Coli	Negative/10g	USP 43 <61>				
Salmonella	Negative/25g	USP 43 <61>				
S.Aureus	Negative/25g	USP 43 <61>				
Storage & Shelf Life						
Package	25kgs/drum	25kgs/drum				
Shelf life	The shelf life for the product is 24 months from date of production. Use it as soon as possible once it is					
	opened.	opened.				
Storage	Store in unopened original package under clean and dry condition, away from sunlight					

2.Origin & ingredient							
Country of origin of the product: China	Origin statement: available ⊠						
This product is a pure material		This product is a comp	pound material $\;\square$				
Animal Origin			Specific Source: /				
	□porcine		Specific Source: /				
	□ovine		Specific Source: /				
	□Others:		Specific Source: /				
Synthetic	×	Starting material: S.R	- epichlorohydrine	origin: China			
	☐ Catalysis By Enzymes		Name Of Enzyme: /				
Biotechnological processing			Sources Of Enzymes: /				
	☐ Fermentation		Source Of Medium: /				
			Strain: /				
	Botanical Nar	ne:	/				
Botanical Origin Part:			/				
	Wild Or Cultivated:		/				
Country Of Origin:		rigin:	/				
	Solvent Used:		/				

3.Nutrition Data	
Nutritional Composition	⊠Per 100g □Per Serving
□Energy(Kj) ⊠ Energy(Kcal)	Okcal
Fat(G)	0
Carbohydrates(G)	0
Protein(G)	0
Sodium (Mg)	0
Remarks: Nutrition Data Are Obtained By 3 <sup>rd</sup> Party Lab; Test	ed On A Yearly Basis



4. GMO Declaration	YES	NO
The product does not contain or consist of GMO		$\boxtimes$
The product is not produced from GMO or not contain ingredients produced from GMO		$\boxtimes$
(irrespective of whether there is NDA or protein of GM origin in the final production)		
This product is not produced by means of GM microorganism including precursor		$\boxtimes$
substances, e.g. with GMOs or Genetically Modified microorganisms processing		
aids(bacteria, yeast,)		
This product is not produced with the help of enzymes, which were obtained from GMOs		$\boxtimes$
Does the product contain any ingredients from animal?		$\boxtimes$
If yes, are genetically modified crops contained in the feed for the animal?		$\boxtimes$
We confirm that this product complies with regulations EC/18292003 and EC1830/2003 and I		
statement available		

### 5. Allergen Declaration

We have carefully reviewed this product according to EU Regulation 1169/2011 and modifications and confirm the following:

	Direct incorporation as a base raw material or in a derivative form (don't forget the carriers, the additives and the processing aids)		CROSS CONTAMINATION					
			Presence on the production line		Presence on the production workshop		Presence on the production factory	
	Yes (precise nature)	No	Yes (precise the nature)	No	Yes (precise the nature)	No	Yes (precise the nature)	No
Cereals containing gluten(1) and products thereof		N		N		N		N
Crustaceans and products thereof		N		N		N		N
Eggs and products thereof		N		N		N		N
Fish and products thereof (2)		N		N		N		N
Peanuts and products thereof		N		N		Ν		N
Soybeans and products thereof (3)		N		N		N		N
Milk and products thereof (including lactose)(4)		N		N		N		N
Nuts (5) or products thereof		N		N		Ζ		N
Celery and products thereof		N		N		Ν		N
Mustard and products thereof		N		N		Ν		N
Sesame seeds and product thereof		N		N		Ν		N
Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10 mg/l expressed as SO2		N		N		N		N
Lupines and products thereof		N		N		N		N
Mollusc and product thereof		N		N		N		N

<sup>(1)</sup> Cereals which contain gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) except: wheat-based glucose syrups including dextrose, wheat-based maltodextrins, glucose syrups based on barley, cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;

<sup>(2)</sup> Except: fish gelatine used as carrier for vitamin or carotenoid preparations, fish gelatine or Isinglass used as fining agent in beer and wine;



- (3) Except fully refined soybean oil and fat, natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources; vegetable oils derived phytosterols and phytosterol esters from soybean sources; plant stanol ester produced from vegetable oil sterols from soybean sources;
- (4) Except when used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages, lactitol;
- (5) almond (Amydalus communis L.) hazelnuts (Corylus avellana), walnut (Juglans regia), cashew (Anacardium occidentale), pecan nuts (Carya illinaiesis), brazil nut (Bertholletia excelsa), pistachio nut (Pistacia vera), macadamia nut and queensland nut (Macadamia terniflora) and products thereof, except nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;

6.NON IRRAIDATION					
(According to EU directive 1999/2/EC & 1999/3/EC)					
This product has been treated with ionising radiation					
The raw materials we used for this product have been treated with ionising	□YES	⊠NO			
radiation.					
We confirm above Non-Irradiation statement is available		×			
7.NANOMATERIAL					
(according to EU Regulation (EU) No. 1169/2011)	T				
This product contains any nanomaterials as defined in EU food legislation	□YES	⊠NO			
This product has been made with nanotechnology	□YES	⊠NO			
We confirm above Non-Nanomaterial statement is available	×				
8. Residual Solvents					
(according to UE Directive 2009/32 modified by(UE)2010/59; EP5.4;USP476;ICH Q3C	(R7))				
For this product following solvents are used during production process:					
Solvent A: max residual level:	]	⊠solvent used			
		□solvent not used			
	⊠EP 7.0				
We confirm solvent residual of this product complies with:	⊠USP <476	>			
	⊠ICH Q3C(F	R7)			
☑ Directive 2010/59/EU					
⊠NA					
We confirm Solvent residual statement is available					
9.Pesticide residual					
(according to EC 396/2005; EP07; USP <561>)					
This product is of vegetable origin	□YES	⊠NO			
We confirm pesticide residual of this product complies with:	⊠EC 396/	2005			
	⊠EP 07/20	008			
	⊠USP<56	1>			
□N/A					
Pesticide residual statement available					
10.BSE/TSE information					



(according to EU legislation 999/2001; EP general chapter 5.2.8)				
Cattle, sheep, goats and animals that are naturally susceptible to infect with transmissible spongiform encephalopathy agents or susceptible				
to infection through the oral route other than humans and non-human primates are defined as "ESE-relevant animal species				
Pigs ad birds are not naturally susceptible to infection via the oral route; therefor	re, they	are not TSE-relevant animal species. Dogs, rabbits		
and fish are not TES-relevant animal species."				
The product contains ingredients of ruminant origin and no materials derived from	om, or	□YES		
exposed to ruminants affected by or under quarantine for Transmitting Transm	issible	⊠no		
Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE)		□NA		
In the manufacturing of this product, there is raw or source material and / or re	eagent	□YES		
used that is of animal origin i.e. bovine, serum-albumin, enzymes, culture	broths			
including those used to prepare working or master cell tanks		⊠NO		
Equipment/systems/tools use for processing or storage of the material come	s into	□YES		
contact at any time with materials of animal origin (e.g., components of medi	a filler			
used to check such system)		⊠NO		
The material is purified by using solvents, chromatographic media or buffer	s that	□YES		
contain components of animal origin		⊠NO		
We confirm this product complies with:		⊠EU legislation 999/2001 & □EP general chapter		
		5.2.8		
We confirm BSE/TSE statement is available		⊠YES		
11.Contaminants information				
(according to UE regulation NO.1881/2006 and NO.629/2008 as regards maximu	m levels	s for certain contaminants in foodstuff)		
•Aflatoxin B1 <5ppb	⊠YES			
•Aflatoxins B1 + B2 + G1 + G2 <10ppb	□ио			
•Ochratoxin A <15ppb				
The state of the s				
•Melamine	⊠YES			
For polycyclic aromatic hydrocarbons, in cocoa fibre, banana chips, food	⊠YES			
supplements and their preparations, dried herbs and dried spices:	□NO			
•Maximum level of 10 µg/kg of benzo(a)pyrene	□NA			
•50 µg/kg for the sum of PAH4 (PAH4; benzo[a]pyrene,chrysene,				
benz[a]anthracene and benzo[b]fluoranthene) in food supplements				

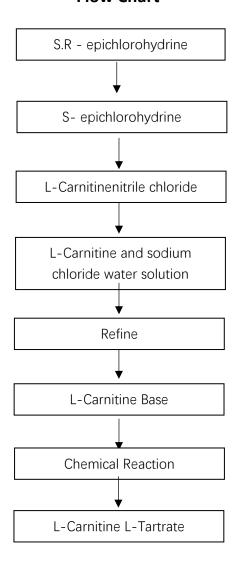
⊠YES

We confirm this product complies with NO.1881/2006 and NO.629/2008 and keep compliance

statement available



# **Flow Chart**





## **Material Safety Data Sheet (MSDS)**

#### 1. PRODUCT IDENTIFICATION

Product Name: L-Carnitine L-Tartrate

INCI Declaration: N/A

**CAS Number:** 36687-82-8

2. PHYSICAL & CHEMICAL PROPERTIES

Melting Point: about 365°C

Boiling Point: not determined

Vapor Pressure: not determined

Vapor Density: not determined

**Density:** about 0.5g/ml **Solubility in water:** insoluble

pH Value: 3.0 - 4.5

Appearance & Odor: white crystal or crystalline powder, odorless

3. STABILITY & REACTIVITY

Chemical Stability: stable when stored light-protected

Incompatibility: none known

Hazardous Decomposition Products: none known; displays

gradual pyrolysis when heated to 120 $_{\circ}\text{C}$  or higher

Hazardous Polymerization: will not occur

#### 4. HANDLING & STORAGE

Avoid contact with eyes. Wash thoroughly after handling. As with all chemicals, good industrial hygiene practices should be followed when handling this material.

Avoid freezing or excessive heat. Do not handle or store near an open flame, heat or other sources of ignition. Keep the container tightly closed and in a cool, well-ventilated place.

#### 5. ACCIDENTAL RELEASE MEASURES

 $Isolate\ spill\ area\ immediately.\ Keep\ unauthorized\ personnel\ away.$ 

Ventilate closed spaces before entering. Do not touch or walk through spilled material. Prevent entry into waterways, sewers, basements or confined areas. Surface may become slippery after spillage. Use vacuum or broom sweeping and remove to disposal container. If damp, flush with water.

#### 6. EXPOSURE CONTROLS & PERSONAL PROTECTION

**Respiratory Protection:** Where exposure likely exceeds acceptable criteria, use NIOSH/OSHA-approved respiratory equipment. **Protective Clothing:** Gloves recommended to prevent skin contact. Safety glasses, goggles, or face shield recommended for eye protection.

Other Protective Measures: Employees must practice good personal hygiene, washing exposed areas of skin several times daily and laundering contaminated clothing before re-use.

#### 7. HAZARDS IDENTIFICATION

General: Non hazardous and non combustible.

Inhalation: Not a primary route of entry. Mists and vapors may cause dizziness (alcohol)

Eye Contact: May cause slight irritation. Irrigate eye with water. Seek medical attention if symptoms persist.

Skin Contact: Not a skin irritant.



#### 8. FIRST AID MEASURES

Eyes: Irrigate eyes with a heavy stream of water for at least 15 to 20 minutes. If irritation persists get medical attention.

**Skin:** Wash exposed areas of the body with soap and water.

Inhalation: Remove from area of exposure. If breathing is difficult, give oxygen. Seek medical attention if symptoms persist.

**Ingestion:** If gastrointestinal symptoms develop, consult medical personnel.

#### 9. FIRE FIGHTING MEASURES

Flammability Limits: None known
Unusual Fire Hazard: None known

**Fire Fighting Procedures:** Firefighters should wear full firefighting turn-out gear (full Bunker gear) including NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

#### 10. TOXICOLOGICAL INFORMATION

Acute Toxicity: LD50 >4 g/kg (oral, rats)

**Subchronic Toxicity:** No pathological findings were observed when 1 g/kg was continually administered to rats for 5 weeks **Chronic Toxicity:** No pathological findings were observed when 0.6 g/kg was continually administered to rats for 26 weeks

# **Teratogenicity:** not teratogenic effects observed in rats **11. DISPOSAL CONSIDERATIONS**

Storage and disposal must be in accordance with applicable local,

state & federal disposal regulations. Characterization and compliance with applicable laws are the responsibility solely of the generator.

#### 12. TRANSPORT INFORMATION

General: not regarded as hazardous material

DOT Shipping Name: Refer to corresponding hazard class

ADR/RIC Code: Refer to corresponding hazard class

Sea Transport IMDG Code: Refer to corresponding hazard class

Air Transport IATA: Refer to corresponding hazard class

#### 13. DISCLAIMER

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process. Such information is to be the best of the company s knowledge and believed accurate and reliable as of the date indicated. However, no representation, warranty or guarantee of any kind, express or implied, is made as to its accuracy, reliability or completeness and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of use. It is the user's responsibility to satisfy himself as to the suitableness & completeness of such information for his own particular use.