

Product Technical Data Sheet	
 Product name: Acetyl L-Carnitine HCL	AC code: AC02321e

1.Technical Data Sheet		
Chemical Name	(R) 2-(acetyloxy)-3-carboxy-N,N,N-trimethyl propanaminium chloride	
CAS number	5080-50-2	
Molecular Weight	239.70	
Molecular Formula	C9H18ClNO4	
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 no less than 98.5% assay		
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	98.5 ~ 101.0%	Titration
Loss on Drying	≤ 0.5%	Ch.P Appendix <0831>
PH	2.0 ~ 3.0	Ch.P Appendix <0631>
Specific Rotation	-26.0° ~ -29.0°	Ch.P Appendix <0621>
Residue on Ignition	≤0.5%	Ch.P Appendix <0841>
Solvent of Residue	≤5000ppm	Ch.P Appendix <0861>
Heavy metals		
Total Heavy Metals	≤10 ppm	Ch.P Appendix <0821>
Lead	≤3.0 ppm	AAS
Arsenic	≤1.0 ppm	AAS
Cadmium	≤1.0 ppm	AAS
Mercury	≤0.1 ppm	AAS
Microorganism		
Total Plate Count	≤1,000 cfu/g	Ch.P Appendix <1106>

Total Molds & Yeasts	≤100 cfu/g	Ch.P Appendix <1106>
E.Coli	Negative/10g	Ch.P Appendix <1106>
Salmonella	Negative/25g	Ch.P Appendix <1106>
S.Aureus	Negative/25g	Ch.P Appendix <1106>
Storage & Shelf Life		
Package	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.	
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 compound material ☐	
Animal Origin	☐ bovine	Specific Source: /	
	☐ porcine	Specific Source: /	
	☐ ovine	Specific Source: /	
	☐ Others:	Specific Source: /	
Synthetic	☒	Starting material: S.R - epichlorohydrine	origin: China
Biotechnological processing	☐ Catalysis By Enzymes	Name Of Enzyme: / Sources Of Enzymes: /	
	☐ Fermentation	Source Of Medium: / Strain: /	
Botanical Origin	Botanical Name:	/	
	Part:	/	
	Wild Or Cultivated:	/	
	Country Of Origin:	/	
	Solvent Used:	/	

3.Nutrition Data

Nutritional Composition	☒ Per 100g	☐ Per Serving
☐ Energy(Kj) ☒ Energy(Kcal)	0kcal	
Fat(G)	0	
Carbohydrates(G)	0	
Protein(G)	0	
Sodium (Mg)	0	
Remarks: Nutrition Data Are Obtained By 3 rd Party Lab; Tested On A Yearly Basis		

4. GMO Declaration

	YES	NO
The product does not contain or consist of GMO	☐	☒

The product is not produced from GMO or not contain ingredients produced from GMO (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 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	☐	☒
Does the product contain any ingredients from animal?	☐	☒
If yes, are genetically modified crops contained in the feed for the animal?	☐	☒
We confirm that this product complies with regulations EC/1829/2003 and EC1830/2003 and keep NON-GMO 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		N		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		N		N
Celery and products thereof		N		N		N		N
Mustard and products thereof		N		N		N		N
Sesame seeds and product thereof		N		N		N		N
Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10 mg/l expressed as SO ₂		N		N		N		N
Lupines and products thereof		N		N		N		N
Mollusc and product thereof		N		N		N		N

- (1) 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;
- (2) 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 (*Amygdalus communis* L.) hazelnuts (*Corylus avellana*), walnut (*Juglans regia*), cashew (*Anacardium occidentale*), pecan nuts (*Carya illinoensis*), 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 IRRADIATION		
(According to EU directive 1999/2/EC & 1999/3/EC)		
This product has been treated with ionising radiation	☐ YES	☒ NO
The raw materials we used for this product have been treated with ionising radiation.	☐ YES	☒ NO
We confirm above Non-Irradiation statement is available	☒	

7. NANOMATERIAL		
(according to EU Regulation (EU) No. 1169/2011)		
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	
We confirm solvent residual of this product complies with:	☒ EP 7.0 ☒ USP <476> ☒ ICH Q3C(R7) ☒ Directive 2010/59/EU ☒ NA	
We confirm Solvent residual statement is available	☒	

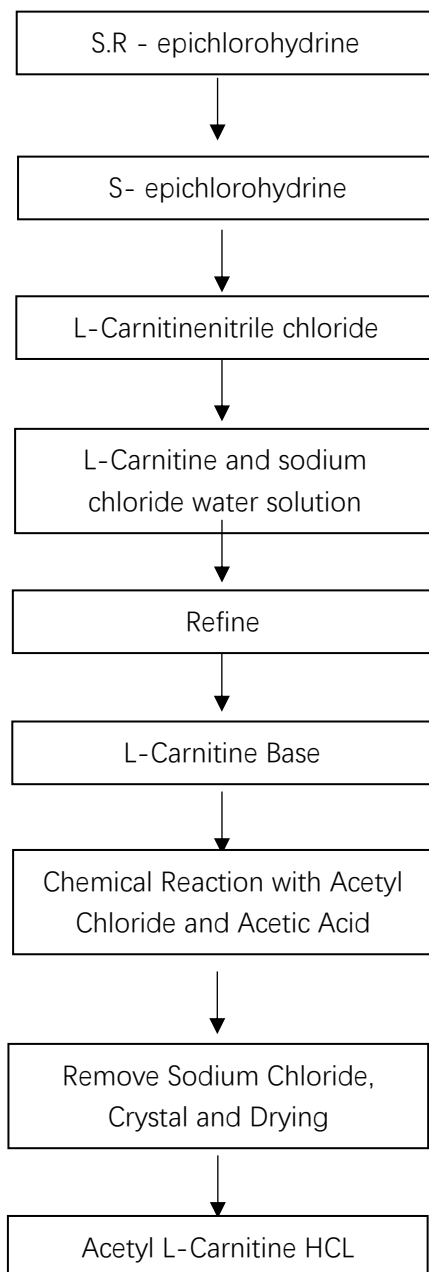
9. Pesticide residual		
(according to EC 396/2005; EP07; USP <561>)		
This product is of vegetable origin	☐ YES ☒ NO	
We confirm pesticide residual of this product complies with:	☒ EC 396/2005 ☒ EP 07/2008 ☒ USP <561> ☐ N/A	
Pesticide residual statement available	☒	

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 and birds are not naturally susceptible to infection via the oral route; therefore, they are not TSE-relevant animal species. Dogs, rabbits and fish are not TSE-relevant animal species."	
The product contains ingredients of ruminant origin and no materials derived from, or exposed to ruminants affected by or under quarantine for Transmitting Transmissible Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE)	☐ YES ☒ NO ☐ NA
In the manufacturing of this product, there is raw or source material and / or reagent used that is of animal origin i.e. bovine, serum-albumin, enzymes, culture broths including those used to prepare working or master cell tanks	☐ YES ☒ NO
Equipment/systems/tools use for processing or storage of the material comes into contact at any time with materials of animal origin (e.g., components of media filler used to check such system)	☐ YES ☒ NO
The material is purified by using solvents, chromatographic media or buffers that contain components of animal origin	☐ YES ☒ 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 maximum levels for certain contaminants in foodstuff)	
•Aflatoxin B1 <5ppb •Aflatoxins B1 + B2 + G1 + G2 <10ppb •Ochratoxin A <15ppb	☒ YES ☐ NO ☐ NA
•Melamine	☒ YES
For polycyclic aromatic hydrocarbons, in cocoa fibre, banana chips, food supplements and their preparations, dried herbs <i>and dried spices</i> : •Maximum level of 10 µg/kg of benzo(a)pyrene •50 µg/kg for the sum of PAH4 (PAH4; benzo[a]pyrene, chrysene, benz[a]anthracene and benzo[b]fluoranthene) in food supplements	☒ YES ☐ NO ☐ NA
We confirm this product complies with NO.1881/2006 and NO.629/2008 and keep compliance statement available	☒ YES

Flow Chart



Material Safety Data Sheet (MSDS)

1. PRODUCT IDENTIFICATION

Product Name: Acetyl L-Carnitine HCL

INCI Declaration: N/A

CAS Number: 5080-50-2

2. PHYSICAL & CHEMICAL PROPERTIES

Melting Point: about 194°C

Boiling Point: not determined

Vapor Pressure: not determined

Vapor Density: not determined

Density: about 0.5g/ml

Solubility in water: insoluble

pH Value: 2.0 – 3.0

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°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 suitability & completeness of such information for his own particular use.