

### Product Technical Data Sheet

<b>Product name: Citicoline Pure</b>	<b>AC code: AC05882a</b>
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#### 1. Technical Data Sheet

Chemical Name	Cytidine diphosphate-choline, cytidine 5'-diphosphocholine
CAS number	987-78-0
Molecular weight	488.32
Molecular Formula	C14H26N4O11P2
Compliance (Food / Pharmacopoeia / FCC / Feed)	Food / Pharmacopoeia / Cosmetic
Source (animal, plant, mineral, petrochemical)	Bio-Synthetic

**Brief introduction:**

Citicoline is an intermediate in the generation of phosphatidylcholine from choline, a common biochemical process in cell membranes. Citicoline is naturally occurring in the cells of human and animal tissue, in particular the organs.

Citicoline is available as a supplement in over 70 countries. When taken as a supplement, citicoline is hydrolyzed into choline and cytidine in the intestine.[2] Once these cross the blood–brain barrier it is reformed into citicoline by the rate-limiting enzyme in phosphatidylcholine synthesis, CTP-phosphocholine cytidyltransferase

Item	Standard	Analysis Method
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#### Appearance & Solubility

Appearance	The product is white crystal or crystalline powder, odorless
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#### Typical Analysis

Identification	1) Retention Time 2) Infrared Absorption Spectrum 3) The aqueous solution reaction	CP2020
Assay	98.0% ~ 102.0%	Enterprise Standard
Loss on Drying	≤ 5.0%	Enterprise Standard
PH	2.5 – 3.5	Enterprise Standard
Chloride	≤0.05%	Enterprise Standard
Limit of ammonium salt	≤0.05%	Enterprise Standard
Limit of iron salt	≤0.01%	Enterprise Standard
Limit of phosphate	≤0.1%	Enterprise Standard
Limit of arsenic salt	≤0.0001%	Enterprise Standard
Related Substances	5'-CMP	≤0.30%
	Single Impurity	≤0.20%
	Total Impurity	≤0.70%
Residual Solvent	Ethanol	≤ 0.5%
	Methanol	≤ 0.3%
	Acetone	≤ 0.5%

#### Heavy metals



Total Heavy Metals	≤5 ppm	USP <233>
Lead	≤3.0 ppm	USP <233>
Arsenic	≤1.0 ppm	USP <233>
Cadmium	≤1.0 ppm	USP <233>
Mercury	≤0.1 ppm	USP <233>
<b>Microorganism</b>		
Aerobic bacterial count	≤1,000 cfu/g	USP <61>
Total Molds & Yeasts	≤100 cfu/g	USP <61>
E.Coli	Negative/10g	USP <62>
Salmonella	Negative/25g	USP <62>
<b>Storage &amp; Shelf Life</b>		
Package	20kgs/carton or 20kgs/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 <input checked="" type="checkbox"/>		This product is a compound material <input type="checkbox"/>	
Animal origin	<input type="checkbox"/> bovine	Specific Source: /	
	<input type="checkbox"/> porcine	Specific Source: /	
	<input type="checkbox"/> ovine	Specific Source: /	
	<input type="checkbox"/> Others:	Specific Source: /	
Synthetic	<input checked="" type="checkbox"/>	Starting material: 5'-CMP	origin: China
Biotechnological processing	<input type="checkbox"/> Catalysis By Enzymes	Name Of Enzyme: / Sources Of Enzymes: /	
	<input type="checkbox"/> Fermentation	Source Of Medium: / Strain: /	
Botanical Origin	Botanical Name:	/	
	Part:	/	
	Wild Or Cultivated:	/	
	Country Of Origin:	/	
	Solvent Used:	/	

## 3.Nutrition Data

Nutritional Composition	<input checked="" type="checkbox"/> Per 100g <input type="checkbox"/> Per Serving
<input type="checkbox"/> Energy(Kj) <input checked="" type="checkbox"/> Energy(Kcal)	0kcal
Fat(G)	0
Carbohydrates(G)	0
Protein(G)	0
Sodium (Mg)	0



Remarks: Nutrition Data Are Obtained By 3<sup>rd</sup> Party Lab; Tested On A Yearly Basis

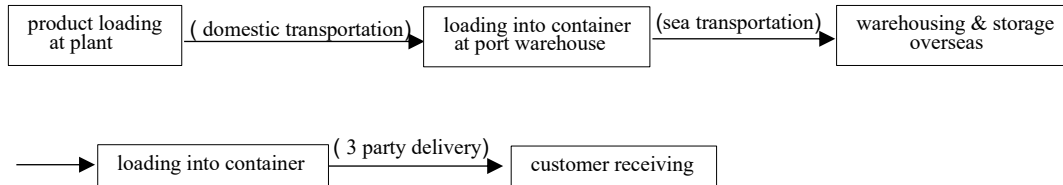
4.Manufacture Details	
Manufacturer Name:	Yantai Acerbio Technology Ltd
Address:	Tianmu Road, Laiyang Development District, Yantai, Shandong
Main Products:	Bio-synthetic and Fermentation Products including Coenzyme Q10, Hyaluronic Acid, L- Ergothioneine
Capacity Of Production	50mt per year
Number Of Employees in Production: 60	Number Of Employees in QA / QC.:12
Quality And Food Safety Management System Certificated By Accredited Authority. E.G.: ISO Series, GFSI Series HACCP GMP、CGMP FAMI-QS、GMP+	ISO9001 Series: <input type="checkbox"/> ISO9001 <input type="checkbox"/> ISO22000 <input type="checkbox"/> ISO14001 <input type="checkbox"/> ISO45000  GFSI Series: <input checked="" type="checkbox"/> BRC <input type="checkbox"/> FSSC22000 <input type="checkbox"/> IFS <input type="checkbox"/> SQF  <input type="checkbox"/> GMP <input type="checkbox"/> HACCP <input type="checkbox"/> FAMI-QS <input type="checkbox"/> GMP+
Product Related Certificates	<input checked="" type="checkbox"/> HALAL <input type="checkbox"/> KOSHER <input type="checkbox"/> IP <input type="checkbox"/> ORGANIC
Suitable For Vegan	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
We Confirm Above Mentioned Certificates Or Related Statement And Keep Available <input checked="" type="checkbox"/>	

5.Process quality and food safety	
Flow chart: This product specification has listed the detailed process flow chart of each step of the actual production process from raw material pretreatment to finished product warehousing, including possible additives, processing aids, steps to remove foreign matters, CCP, water used, compressed air etc.	Integrity flow chart available <input checked="" type="checkbox"/>
CCP in place	
CCP info.	CL Location in process
Foreign body control	
Have implemented control procedures for glass, fragile plastic materials <input checked="" type="checkbox"/>	
Pest control	
Conducted by manufacturer: <input checked="" type="checkbox"/> by external contractor <input type="checkbox"/> Name of contractor:	
Batch no.& traceability	
Batch size:	500kgs
Batch definition:	Signification of the batch no. by an example: In 789093. If you subtract 7, 8, 9, 0, 9 and 3, you get the last two digits of the year, month, and date in the production date, such as 2021/09/06, that is the production date

We confirm that we perform batch and traceability management on the whole process from raw material receiving, production process, storage and transportation, by focusing on raw materials, semi-finished products, production processing and transportation, related records and product labels. Take traceability exercise on a annual basis.

#### Supply chain custody

list all the stages in the process of supply chain including detail of every link back to farm, field or ocean. Every time the raw material is moved, paid for, handled, stored or processed, and final to customer



6. GMO declaration	YES	NO
The product does not contain or consist of GMO	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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,..)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
This product is not produced with the help of enzymes, which were obtained from GMOs	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does the product contain any ingredients from animal?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, are genetically modified crops contained in the feed for the animal?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
We confirm that this product complies with regulations EC/1829/2003 and EC1830/2003 and keep NON-GMO statement available		<input checked="" type="checkbox"/>

#### 7. 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
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 SO2		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;

<b>8. NON IRRADIATION</b>		
(According to EU directive 1999/2/EC & 1999/3/EC)		
This product has not been treated with ionising radiation	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
None of the raw materials we used for this product have been treated with ionising radiation.	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
We confirm above Non-Irradiation statement is available	<input checked="" type="checkbox"/>	

<b>9. NANOMATERIAL</b>		
(according to EU Regulation (EU) No. 1169/2011)		
This product does not contain any nanomaterials as defined in EU food legislation	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
This product has not been made with nanotechnology	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
We confirm above Non-Nanomaterial statement is available	<input checked="" type="checkbox"/>	

<b>10. Residual solvents</b>		
(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:		<input checked="" type="checkbox"/> solvent used <input type="checkbox"/> solvent not used
We confirm solvent residual of this product complies with:	<input checked="" type="checkbox"/> EP 7.0 <input checked="" type="checkbox"/> USP <476> <input checked="" type="checkbox"/> ICH Q3C(R7) <input type="checkbox"/> Directive 2010/59/EU <input checked="" type="checkbox"/> NA	
We confirm Solvent residual statement is available	<input checked="" type="checkbox"/>	

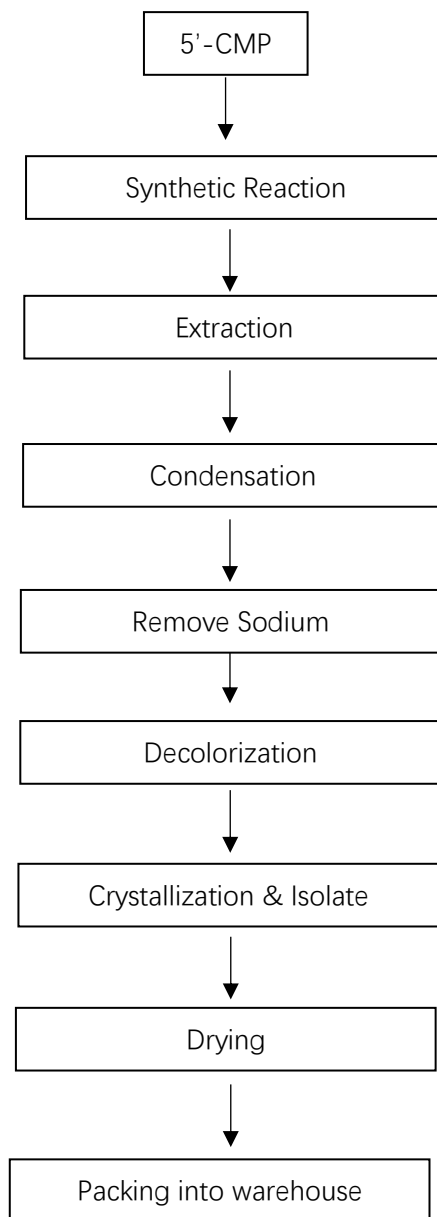
<b>11. Pesticide residual</b>
(according to EC 396/2005; EP07; USP <561>)

This product is of vegetable origin	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
We confirm pesticide residual of this product complies with:	<input checked="" type="checkbox"/> EC 396/2005 <input checked="" type="checkbox"/> EP 07/2008 <input checked="" type="checkbox"/> USP<561> <input type="checkbox"/> N/A
Pesticide residual statement available	<input checked="" type="checkbox"/>

<b>12. BSE/TSE information</b>	
(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 no 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)	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> NA
In the manufacturing of this product, there is no any 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	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
Equipment/systems/tools use for processing or storage of the material do not come into contact at any time with materials of animal origin (e.g., components of media filler used to check such system)	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
The material is not purified by using solvents, chromatographic media or buffers that contain components of animal origin	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
We confirm this product complies with:	<input checked="" type="checkbox"/> EU legislation 999/2001 & <input type="checkbox"/> EP general chapter 5.2.8
We confirm BSE/TSE statement is available	<input checked="" type="checkbox"/> YES

<b>13. Contaminants information</b>	
(according to UE regulation NO.1881/2006 and NO.629/2008 as regards maximum levels for certain contaminants in foodstuff)	
<ul style="list-style-type: none"> <li>•Aflatoxin B1 &lt;5ppb</li> <li>•Aflatoxins B1 + B2 + G1 + G2 &lt;10ppb</li> <li>•Ochratoxin A &lt;15ppb</li> </ul>	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
•Melamine	<input checked="" type="checkbox"/> YES
For polycyclic aromatic hydrocarbons, in cocoa fibre, banana chips, food supplements and their preparations, dried herbs <i>and dried spices</i> : <ul style="list-style-type: none"> <li>•Maximum level of 10 µg/kg of benzo(a)pyrene</li> <li>•50 µg/kg for the sum of PAH4 (PAH4; benzo[a]pyrene, chrysene, benz[a]anthracene and benzo[b]fluoranthene) in food supplements</li> </ul>	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
We confirm this product complies with NO.1881/2006 and NO.629/2008 and keep compliance statement available	<input checked="" type="checkbox"/> YES

**Flow Chart**





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## Material Safety Data Sheet (MSDS)

### Citicoline Sodium

#### 1. PRODUCT IDENTIFICATION

**Product Name:** Citicoline

**INCI Declaration:** N/A

**CAS Number:** 987-78-0

#### 2. PHYSICAL & CHEMICAL PROPERTIES

**Melting Point:** about 48°C (124°F)

**Boiling Point:** not determined

**Vapor Pressure:** not determined

**Vapor Density:** not determined

**Density:** about 0.5g/ml

**Solubility in water:** insoluble

**pH Value:** 2.5 - 3.5

**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°C or higher

**Hazardous Polymerisation:** 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.

**Ingestion:** No specific hazard known. CoQ10 can be consumed up to 5-10 mg/d through food products.



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## 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.