

Product Technical Data Sheet

Product name: Citicoline Sodium	AC code: AC05881d
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1. Technical Data Sheet		
Chemical Name		cytidine 5'-(trihydrogen diphosphate) p'-(2-(trimethylammonio)ethyl) ester inner salt monosodium salt; sodium 5'-O-[[{2-(trimethylammonio)ethoxy}phosphinato}oxy]phosphinato]cytidine
CAS number		33818-15-4
Molecular weight		510.31
Molecular Formula		C14H25N4NaO11P2
Compliance (Food / Pharmacopoeia / FCC / Feed)		Food / Pharmacopoeia / Cosmetic
Source (animal, plant, mineral, petrochemical)		Bio-Synthetic
Brief introduction: Citicoline sodium is an essential intermediate in the synthesis of the major phospholipid of the cell membranes. It can be used as a nutritional supplement with potential neuroprotective and nootropic activity.		
Item	Standard	Analysis Method
Appearance & Solubility		
Appearance	The product is white crystal or crystalline powder, odorless	
Clarity	Take 1g of this product, dissolve in water to 8ml, shake and observe whether the solution is clear	
Typical Analysis		
Identification	The retention time of main peak of test and standard are concordant	
Assay	≥98.0%	
Loss on Drying	≤6.0%	
PH	6.0 – 7.5	
Chloride	≤0.05%	
Limit of ammonium	≤0.05%	
Limit of iron salt	≤0.01%	
Limit of phosphate	≤0.1%	
Limit of arsenic salt	≤0.0001%	
Related Substances	5'-CMP	≤0.30%
	Single Impurity	≤0.20%
	Total Impurity	≤0.70%
Residual Solvent	Ethanol	≤5000ppm
	Methanol	≤3000ppm
	Acetone	≤5000ppm
	Toluene	≤890ppm

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>
Microorganism		
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>
Storage & Shelf Life		
Package	20kgs/carton	
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 <input checked="" type="checkbox"/>	
This product is a pure material <input checked="" type="checkbox"/>		This product is a compound material <input type="checkbox"/>	
The product's composition is 100% Citicoline			
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 rd 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	200mt 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 an 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	
<div style="display: flex; align-items: center; justify-content: space-around;"> <div style="border: 1px solid black; padding: 5px; text-align: center;">product loading at plant</div> <div style="text-align: center;">(domestic transportation)</div> <div style="border: 1px solid black; padding: 5px; text-align: center;">loading into container at port warehouse</div> <div style="text-align: center;">(sea transportation)</div> <div style="border: 1px solid black; padding: 5px; text-align: center;">warehousing & storage overseas</div> </div> <div style="display: flex; align-items: center; justify-content: space-around;"> <div style="text-align: center;">→</div> <div style="border: 1px solid black; padding: 5px; text-align: center;">loading into container</div> <div style="text-align: center;">(3 party delivery)</div> <div style="border: 1px solid black; padding: 5px; text-align: center;">customer receiving</div> </div>	

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	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;

8. NON IRRADIATION

(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"/>	

9. NANOMATERIAL

(according to EU Regulation (EU) No. 1363/2013)

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"/>	

10. 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:		<input checked="" type="checkbox"/> solvent used <input type="checkbox"/> solvent not used
Solvent A:	max residual level:	
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"/>

11. Pesticide residual	
(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"/>

12. BSE/TSE information	
(according to EU No. 2019/319; 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

13. Contaminants information

(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"> ●Aflatoxin B1 <5ppb ●Aflatoxins B1 + B2 + G1 + G2 <10ppb ●Ochratoxin A <15ppb 	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
●Melamine Free	<input checked="" type="checkbox"/> YES
●Dioxins, Furans , Polychlorinated Biphenyls Free	<input checked="" type="checkbox"/> YES
<p>For polycyclic aromatic hydrocarbons, in cocoa fibre, banana chips, food supplements and their preparations, dried herbs <i>and dried spices</i>:</p> <ul style="list-style-type: none"> ●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 	<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	

14. WADA STATEMENT

We confirm that no products made or stored within our facility contain any of the prohormones, stimulants, steroids, etc. that are on the current WADA list.

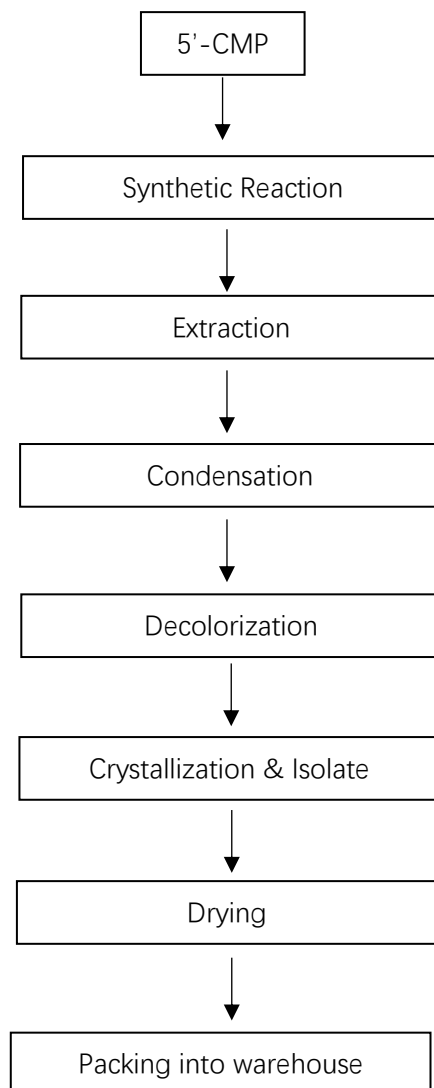
15. ETO FREE STATEMENT

We hereby confirm that we do not use ethylene oxide (ETO), 2-Chloroethanol nor any other chemical sterilizing agent during the manufacturing, storage or transport of our product.

16. Other statements

We confirm Nitrates of this product complies with EU No 1258/2011	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
We confirm Mycotoxins / Aflatoxins of this product complies with EU No 165/2010	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
We confirm 3-MCPD of this product complies with EU No. 2020/1322	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
We confirm Pyrrolizidine alkaloids of this product complies with Regulation (EU) 2020/2040	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA

Flow Chart





Material Safety Data Sheet (MSDS)

Citicoline Sodium

1. PRODUCT IDENTIFICATION

Product Name: Citicoline Sodium

INCI Declaration: N/A

CAS Number: 33818-15-4

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: 6.0 – 7.5

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.

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.