

Product Data Sheet

Product name: I-Biomax Coenzyme Q10 40%
AC Code: AC05082c

1. Technical Data Sheet

CAS number	303-98-0	
Compliance (Food/ Pharmacopoeia /FCC/Feed)	Food (Enterprise Standard)	
Source (animal, plant, mineral, petrochemical)	Fermentation	
Item	Standard	Analysis Method
Sensory		
Appearance	Yellow to orange yellow flowing powder	Visual
Typical Analysis		
Coenzyme Q10 Assay	≥ 40.0%	HPLC
Particle Size	100% pass through sieve 40 mesh 90% pass through sieve 80 mesh	USP <786> Ph.Eur.2.9.12
Water dispersibility	Easily dispersed in the cold water 15°C to form a Uniform and stable	/
Loss on drying	≤ 5.0%	USP <731> Ph.Eur.2.2.32
Heavy Metals		
Heavy metals	≤ 10 ppm max	USP <231> II Ph.Eur.2.4.8
Lead	≤ 2.0 ppm	USP <251> Ph.Eur.2.4.10
Arsenic	≤ 1.0 ppm	USP <211> II Ph.Eur.2.4.2
Cadmium	≤ 1.0 ppm	USP <233>
Mercury	≤ 0.1 ppm	USP <233>
Microorganism		
Total Plate Count	≤ 1,000 CFU/g	USP <2021> Ph.Eur.2.6.12
Yeast and Mold	≤ 100 CFU/g	USP <2021> Ph.Eur.2.6.12
Enterobacterial	≤ 10 CFU/g	USP <2021> Ph.Eur.2.6.13
E. Coli	n.d./10g	
Salmonella	n.d./25g	
Staphylococcus Aureus	n.d./10g	
Package	Packed In 20kgs/Carton or 25kgs/Drum	
Shelf life	2 Year When Properly Stored	
Storage	The product may be stored for 24 months from the date of manufacture in the unopened original container and at room temperature. It should be protected from light, heat, oxygen and moisture. Keep the container	

	tightly closed. Once opened, use contents quickly
Intended Application	Suitable for manufacturing tablets and hard-shell capsules. Also as a food nutrition enhancer for food and beverage

2. Origin & ingredient

Country of origin of the product: China

Origin Statement: available

This Product Is A Pure Material <input type="checkbox"/>		This Product is a Compound Material <input checked="" type="checkbox"/>	
Composition of the products		Coenzyme Q10: 40% Edible vegetable oil, Natural vitamin E, Modified Starch, Maltodextrin, Vitamin C	
Animal Origin	<input type="checkbox"/> Bovine	Specific Source	
	<input type="checkbox"/> Porcine	Specific Source	
	<input type="checkbox"/> Avian,	Specific Source	
	<input type="checkbox"/> Others:	Specific Source:	
Mineral Origin	<input type="checkbox"/>	Specific Source:	
Synthetic	<input type="checkbox"/>	Starting Material:	Origin:
		Starting Material:	Origin:
Biotechnological Processing	<input checked="" type="checkbox"/> Catalysis By Enzymes	Name Of Enzyme: Fermentation from bacteria Sources Of Enzymes:	
	<input type="checkbox"/> Micro -Organisms	Source Of Medium:	
Botanical Origin	Botanical Name:	/	
	Part:	/	
	Wild Or Cultivated:	/	
	Country Of Origin:	China	
	Solvent Used:	Ethanol, Hexane, Ethyl Acetate	

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)	360.0 kcal	
Fat (g)	0	
Carbohydrates (g)	95	
Protein (g)	0	
Sodium (mg)	0	
Dietary Fiber (g/100g)	0	
Moisture Content (g)	4.5	
Potassium (mg/kg)	0	
Calcium (mg/kg)	0	
Iron (mg/kg)	0	
Vitamin A (µg/100g)	0	
Vitamin C (µg/100g)	0	
Vitamin D3 (µg/100g)	0	

Remarks: Nutrition data are obtained by 3rd party lab; tested on a yearly basis

4.Manufacture details	
Manufacturer name:	Yantai Runshuo Biotech Technology Ltd
Address:	Tianmu Road Development Zone, Laiyang City Shandong Province 265200, China
Main products:	Acerbio, Vidaprotein
Capacity of production	1,000mt
Number Of Employees In Production: 30	Number Of Employees In QA/QC.: 6
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 checked="" type="checkbox"/> ISO22000 <input type="checkbox"/> ISO14001 <input type="checkbox"/> ISO45000 GFSI Series: <input 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 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

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	CL
1. Emulsification	Enterprise Standard, Temperature: 80°C Time: 3 hours
2. Micro-emulsion	Temperature: 220°C Time: 5 minutes
...	
Foreign Body Control	
Have Implemented Control Procedures For Glass, Fragile Plastic Materials <input checked="" type="checkbox"/>	
<input checked="" type="checkbox"/> Sieve	Location: Before Packing Mesh Size: 0.2mm
<input checked="" type="checkbox"/> Magnetic Device	Location: Before Packing Magnetic Strength: 13400Gauss
<input type="checkbox"/> Filter Bag Or Filter Membrane	Location: Aperture Of Filtering Device:
Pest Control	
Conducted By Manufacturer <input type="checkbox"/>	
By External Contractor <input checked="" type="checkbox"/>	Name Of Contractor:

Inspection Frequency: 1 Time Per Year	
Batch No.& Traceability	
Batch Size:	1,000kgs
Batch Definition:	Signification Of The Batch No. By An Example: Abbr. Of Customer+Year+Month+ Batch Sequence Produced By This Day ACER20201205: Acer+2020year+12month+05(5 th Batch Produced On 5th)
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	
<pre> graph LR A[product loading at plant] -- "(domestic transportation)" --> B[loading into container at port warehouse] B -- "(sea transportation)" --> C[warehousing & storage overseas] D[loading into container] -- "(3 party delivery)" --> E[customer receiving] </pre>	

GMO Declaration	YES	NO
The Product Contain Or Consist Of GMO	<input type="checkbox"/>	<input checked="" type="checkbox"/>
The Product Is Produced From GMO Or 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 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 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? If Yes, Are Genetically Modified Crops Contained In The Feed For The Animal?	<input type="checkbox"/> <input type="checkbox"/>	<input checked="" 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"/>

6. 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 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;

7. Non Irradiation

(According To Eu Directive 1999/2/EC & 1999/3/EC)

This Product Has 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"/>	

8. Nanomaterial

(According To Eu Regulation (Eu) No. 1169/2011)

This Product Does Contain Any Nanomaterials As Defined In Eu Food Legislation	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
This Product Has 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"/>	

9. 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
Solvent A: Max Residual Level:		<input type="checkbox"/> Solvent Not Used
Solvent B: Max Residual Level:		
We Confirm Solvent Residual Of This Product Complies With:	<input checked="" type="checkbox"/> EP8.0 <input checked="" type="checkbox"/> USP <476> <input checked="" type="checkbox"/> ICH Q3C(R7) <input checked="" type="checkbox"/> Directive 2010/59/EU	
We Confirm Solvent Residual Statement Is Available	<input checked="" type="checkbox"/>	

10. 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 type="checkbox"/> EC 396/2005 <input checked="" type="checkbox"/> EP 07/2008 <input checked="" type="checkbox"/> USP<561> <input checked="" type="checkbox"/> N/A
Pesticide Residual Statement Available	<input checked="" type="checkbox"/>

11. 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; Therefore, 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, 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 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 Comes 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 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 checked="" type="checkbox"/> EP General Chapter 5.2.8
We Confirm BSE/TSE Statement Is Available	<input checked="" type="checkbox"/> YES

12. Contaminants Information (According To EU 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 ● Melamine 	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA	(Frequency For Surveillance Test Or Batch Test)
For Polycyclic Aromatic Hydrocarbons, In Cocoa Fibre, Banana Chips, Food Supplements And Their Preparations, Dried Herbs And Dried Spices: <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	(Frequency For Surveillance Test Or Batch Test)
We Confirm This Product Complies With NO.1881/2006 And NO.629/2008 And Keep Compliance Statement Available		<input checked="" type="checkbox"/> YES