

Product Data Sheet

Product name: Chondroitin Sulphate Terrestrial EP
Product Code: AC05003e

1. Technical Data Sheet

CAS number	9007-28-8	
Compliance (Food/ Pharmaceutical /FCC/Feed)	Pharmaceutical	
Source (animal, plant, mineral, petrochemical)	Terrestrial	
Item	Standard	Analysis Method
Sensory		
Appearance	White or almost white, hygroscopic powder	Visual
Typical Analysis		
Identification	Infrared absorption spectrophotometry	EP 11.0
Identification	Sodium Reaction	EP 11.0
Identification	Related Substances $\leq 2.0\%$	EP 11.0
Assay	$\geq 95\%$ by CPC (Dry basis)	EP 11.0
Assay	$\geq 90\%$ by HPLC (Dry basis)	Enterprise Standard
Assay	$\geq 75\%$ by Enzymatic-HPLC (Dry basis)	AOAC
Particle Size	100% pass through sieve 80 mesh	EP 2.9.31
Water Solubility	Freely soluble in water, practically insoluble in acetone and in ethanol (96 per cent)	Enterprise Standard
Loss on drying	$\leq 12.0\%$	EP 2.2.32
PH	5.5 ~ 7.5	EP 2.2.3
Chloride	0.5% Max	EP 2.4.4
Protein	$\leq 3.0\%$	EP 2.5.33
Residue on ignition	20% ~ 30%	USP <281>
Specific Rotation	-20°~ -30°	EP 2.2.7
Heavy Metals		
Heavy metals	≤ 10 ppm max	EP 2.4.8
Lead	≤ 3.0 ppm	EP 2.4.8
Arsenic	≤ 1.0 ppm	EP 2.4.8
Cadmium	≤ 1.0 ppm	EP 2.4.8
Mercury	≤ 0.1 ppm	EP 2.4.8
Microorganism		
Total Plate Count	$\leq 1,000$ CFU/g	EP 2.6.12
Yeast and Mold	≤ 100 CFU/g	EP 2.6.12
E. Coli	Negative/g	EP 2.6.13
Salmonella	Negative/10g	EP 2.6.13
A.Aureus	Negative/g	EP 2.6.13
Pseudomonas Aeruginosa	Negative/g	EP 2.6.13
Bile-Tolerant Gram-	Negative/g	EP 2.6.13

Negative Bacteria	
Package	25kgs/Paper Drum
Storage & Shelf Life	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

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"/>	
Composition of the products		100% Chondroitin Sulphate	
Animal Origin	<input checked="" type="checkbox"/> Bovine		
	<input type="checkbox"/> Porcine		
	<input checked="" type="checkbox"/> Chicken		
	<input type="checkbox"/> Others:		
Mineral Origin	<input type="checkbox"/>	Specific Source:	
Synthetic	<input type="checkbox"/>	Starting Material:	Origin:
		Starting Material:	Origin:
Biotechnological Processing	<input type="checkbox"/> Catalysis By Enzymes		Name Of Enzyme: 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

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)	269.2 kcal	
Fat (g)	<0.1	
Carbohydrates (g)	42.1	
Protein (g)	25.2	
Remarks: Nutrition data are obtained by 3 rd party lab; tested on a yearly basis		

4.Process Quality And Food Safety

<p>Flow Chart:</p> <p>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.</p>	Integrity Flow Chart Available <input checked="" type="checkbox"/>
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		

5. 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 checked="" type="checkbox"/> <input type="checkbox"/>	<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"/>

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
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"/> Not Used
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"/> EP 11.0 <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 type="checkbox"/> YES <input checked="" 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 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)	
<p>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</p> <p>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."</p>	
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, Not used <input type="checkbox"/> NA
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)
<p>For Polycyclic Aromatic Hydrocarbons, In Cocoa Fibre, Banana Chips, Food Supplements And Their Preparations, Dried Herbs And Dried Spices:</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	(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	