

Created Date:2021.10.13

Review Date:2021.10.13

Review By:Hannibal

Version No:01

Product Data Sheet			
Product name: Milk Thistle Extract			AC Code: AC03390c
1. Technical Data Sheet			
CAS number	65666-07-1		
Compliance (Food/ Pharmacopoeia /FCC/Feed)	Food (EP)		
Source (animal, plant, mineral, petrochemical)	Plant		
Item	Standard	Analysis Method	
Appearance	Yellow to Yellowish-Brown Powder	Visual	
Odor & Taste	Characteristic	Organoleptic	
Typical Analysis			
Identification	TLC	EP9.0	
Assay (Dried)	Silymarin	≥80%	UV
	Silymarin	40%-80%	HPLC
	Silychristin and silydianin (calculated with reference to total silymarin)	20%-45%	HPLC
	Silybin A + B (calculated with reference to total silymarin)	40%-65%	HPLC
	Isosilybin A + B (calculated with reference to total silymarin)	10%-20%	HPLC
Particle Size	90% Through 80 mesh		USP38<786>
Loss on drying	≤ 5.0%		EP9.0(2.8.17)
Sulphated Ash	≤ 0.5%		EP9.0(2.4.14)
Residual Solvents	Acetone	≤5000ppm	EP9.0(5.4)
	N-hexane	≤290ppm	EP9.0(5.4)
	Ethanol	≤5000ppm	EP9.0(5.4)
Benzo(a)pyrene	≤ 10µg/kg		(EU) 2015/1933
PAH4	≤ 50µg/kg		(EU) 2015/1933
Heavy Metals			
Heavy metals	≤ 10ppm		EP9.0(2.4.27)
Arsenic (As)	≤ 1.0ppm		EP9.0(2.2.58)
Lead (Pb)	≤ 3.0ppm		EP9.0(2.2.58)
Cadmium (Cd)	≤ 1.0ppm		EP9.0(2.2.58)
Mercury (Hg)	≤ 0.1ppm		EP9.0(2.2.58)
Microorganism			
Total Plate Count	<1000cfu/g		EP9.0(2.2.58)
Yeast and Mold	<100cfu/g		EP9.0(2.2.58)
Escherichia Coli	Negative/10g		EP9.0(2.6.12)

Salmonella	Negative /25g	EP9.0(2.6.12)
Package	Packed In 25kgs/Drum	
Shelf life	3 Year When Properly Stored	
Storage	In Tight, Light-resistant and Dry Place. Avoid Direct Sunshine.	

2.Origin & ingredient

Country of origin of the product: China

 Origin Statement: available

Botanical Origin	Botanical Name:	<i>Silybum marianum (L.) Gaertn</i>
	Part:	Seeds
	Solvent Used:	Acetone

3.Nutrition data

Nutritional composition	<input checked="" type="checkbox"/> per 100g	<input type="checkbox"/> per serving
<input checked="" type="checkbox"/> Energy(kJ)	<input type="checkbox"/> Energy(kcal)	1095
Fat (g)		3.8
Carbohydrates (g)		20.3
Protein (g)		1.6
Sodium (mg)		31
Dietary Fiber (g/100g)		72.8
Remarks: Nutrition data are obtained by 3 rd party lab; tested on a yearly basis		

4.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	Location In Process
Vacuum drying Temperature	Temperature: 85°C Time: 6 hours	Before crushing
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: 180µm±7.6µm
<input checked="" type="checkbox"/> Magnetic Device	Location: Before Packing	Magnetic Strength: 13400Gauss
Pest Control		
Conducted By Manufacturer <input checked="" type="checkbox"/>		
By External Contractor <input type="checkbox"/> Name Of Contractor:		
Inspection Frequency: 3 times per month from May to September and 1 times per month From October to April		
Batch No.& Traceability		
Batch Size:	3,000kgs	

Batch Definition:	Signification Of The Batch No. By An Example: Year +Month+Day 20201205: 2020year+12month+05th
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	

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 checked="" type="checkbox"/>
We Confirm That This Product Complies With Regulations EC/18292003 And EC1830/2003 And Keep NON-GMO Statement Available	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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	<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"/>	

7. 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"/>	

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: Acetone Max Residual Level: 5000ppm	<input checked="" type="checkbox"/> Solvent Used
Solvent B: Ethanol Max Residual Level: 5000ppm	<input type="checkbox"/> Solvent Not Used
Solvent C: N-hexane Max Residual Level: 290ppm	
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"/>

9.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 type="checkbox"/> USP<561> <input type="checkbox"/> N/A
Pesticide Residual Statement Available	<input checked="" type="checkbox"/>

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 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

11. 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