



PRODUCT SPECIFICATION

Product name: Milk-Thistle-80-UV-Feed-Grade

AC code: AC30043a

1. Technical Data Sheet

Chemical Name	/		
CAS number	/		
Molecular weight	/		
Molecular Formula	/		
Compliance (Food/ Pharmacopoeial /FCC/Feed)	Feed		
Source (animal, plant, mineral, petrochemical)	plant		
item	standard	Analysis method	Test frequency
Sensory			
APPEARANCE	Light Yellow powder	Visual	each batch
ODOR	Characteristic	organoleptic	each batch
typical analysis			
ASSAY BY HPLC : SILYMARIN	NLT40%	HPLC	each batch
ASSAY BY HPLC: SILYBIN(Silybin+Isosilybin)	NLT30%	HPLC	each batch
POWDER SIZE	95% through 80 mesh	80mesh screen	each batch
BULK DENSITY	0.40 – 0.60 g/mL	CP2015	each batch
LOSS ON DRYING	5.0% Max.	CP2015	each batch
PH	4.5-6	EU	each batch
PESTICIDES	0.2% Max.	396/2005 CE	each batch
BHC	0.01PPM	GC	each batch
DDT	0.01PPM	GC	each batch
ALORIN	0.01PPM	GC	each batch
DIELDRIN	0.01PPM	GC	each batch
ELDRIN	0.01PPM	GC	each batch
ACETONE	0.5%Max.	GC	each batch



ETHANOL	0.3%Max.	GC	each batch
HEXANE	300PPM	EUGC	each batch
Heavy metals			
TOTAL HEAVEY METAL	10 µg/g Max.	CP2015	each batch
ARSENIC (As)	1.0 µg/g Max.	AAS	each batch
CADMIUM (Cd)	1.0 µg/g Max.	AAS	each batch
LEAD (Pb)	3.0 µg/g Max.	AAS	each batch
MERCURY (Hg)	0.1 µg/g Max.	AAS	each batch
Microorganism			
TOTAL PLATE COUNT	≤ 1000 cfu/g	CP2015	each batch
MOLDS AND YEASTS	≤ 100 cfu/g	CP2015	each batch
SALMONELLA	Absence	CP2015	each batch
E. COLI	Absence	CP2015	each batch
STAPHYLOCOCCUS	Absence	CP2015	each batch
Package	25 kg/drum, packing in paper-drums and two sealed plastic-bags inside		
Shelf life	Two years when properly stored		
Storage	Store in a well-closed container away from moisture, direct light and heat		
Intended application	/		
Recommended usage	/		

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"/>	<input type="checkbox"/> bovine	specific source: /	
	<input type="checkbox"/> porcine	specific source: /	
	<input type="checkbox"/> ovine	specific source: /	
	<input type="checkbox"/> Others:	Specific source: /	
Mineral origin <input type="checkbox"/>	<input type="checkbox"/>	specific source: /	
synthetic <input type="checkbox"/>	<input type="checkbox"/>	Starting material:	origin: /
Biotechnological processing <input type="checkbox"/>	<input type="checkbox"/> Catalysis by enzymes	Name of enzyme: / Sources of enzymes: /	
	<input type="checkbox"/> micro -organisms	source of medium:/ strain: /	
Botanical origin <input checked="" type="checkbox"/>	botanical name:	Silybum marianum(L.)Gaertn	
	part:	Seed	
	wild or cultivated:	cultivated	
	country of origin:	China	
	solvent used:	Aceton, Hexane	

For compound material, all compounds are listed (e.g. antioxidants; coating materials and with their functions):

Each ingredient including food additives	Percentage %	Function(e.g. Nutrient, Binder, Diluent, carrier)	Source Material(s)	Country of Origin of the Source Material
Milk-Thistle extract	100%	/	Seed of Silybum marianum(L.)Gaertn	China
processing aid used <input type="checkbox"/>				
Name of processing aids:		Purpose:	Source:	
/				

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
-of which saturated fat acid(g)	
-of which monounsaturated fat acid(g)	
-of which poly-unsaturated fat acid(g)	
-of which linoleic acid (18:2-6)(g)	
-of which linolenic acid (18:3-3)(g)	
-of which trans fatty acids(g)	
-of which free fatty acid(g)	
Carbohydrates(g)	20.3
-of which sugar(g)	
-of which lactose(g)	
-of which polyol(g)	
-of which starch(g)	
Dietary fiber(g)	72.8
Protein(g)	1.6
Sodium mg/100g	31
Potassium	
Calcium	
Magnesium	
Iron	
Vitamin A	
Vitamin C	
Vitamin D	



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

4.Manufacture details

Manufacturer name:	Acetar Bio-Tech Inc.		
Address:	Shenzhou Digital Building, No.20 Zhangba Si Road, Xi'an, 710077, China		
Main products:	Milk-Thistle extract		
Capacity of production	500-700MT per year		
Number of employees in production:	95	Number of employees in QA/QC.:26	
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 checked="" type="checkbox"/> FSSC22000 <input type="checkbox"/> IFS <input type="checkbox"/> SQF <input checked="" type="checkbox"/> GMP <input type="checkbox"/> HACCP <input checked="" type="checkbox"/> FAMI-QS <input type="checkbox"/> GMP+		
Product related certificates	<input checked="" type="checkbox"/> HALAL	<input checked="" type="checkbox"/> KOSHER	<input type="checkbox"/> IP <input type="checkbox"/> ORGANIC
Suitable for vegan	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
<input checked="" type="checkbox"/> FDA registered FDA No. (12777158566)	<input type="checkbox"/> Sedex registered Sedex 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
Raw material acceptance	heavy metal	Raw material check
sieving	80mesh	Before packing
Foreign body control		
Have implemented control procedures for glass, fragile plastic materials <input checked="" type="checkbox"/>		
<input checked="" type="checkbox"/> sieve	Location1: before packing	mesh size: 80mesh



☐ **Pest control**

Conducted by manufacturer: ☒

by external contractor ☐ name of contractor: /

frequency: 2 times per month

tendency analysis: yes, have

Batch no.& traceability

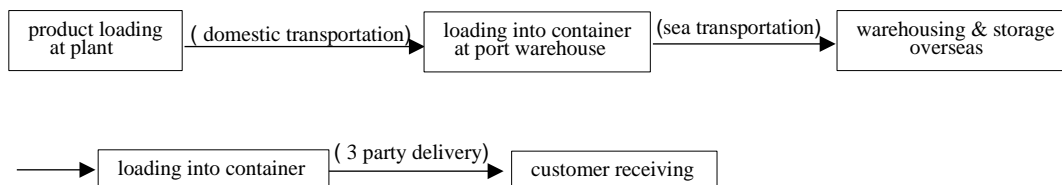
Batch size: 1000KG

Batch definition: Signification of the batch no. by an example:
Year + Month + Serial Number
For example, Pomegranate Extract (40% ellagic acid) , Lot #
180205, which
means this product is the 5th batch manufactured in February,
2018.

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 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 ☒

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 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;

7.NON IRRADIATION		
(according to EU directive 1999/2/EC & 1999/3/EC)		
This product has not been treated with ionising radiation	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
None of the raw materials we used for this product have been treated with ionising radiation.	<input checked="" type="checkbox"/> YES	<input 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 not contain any nanomaterials as defined in EU food legislation	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
This product has not been made with nanotechnology	<input checked="" type="checkbox"/> YES	<input 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: Solvent A: acetone max residual level: 0.5% Solvent B: hexane max residual level: 300ppm	<input checked="" type="checkbox"/> solvent used <input type="checkbox"/> solvent not used
We confirm solvent residual of this product complies with:	<input type="checkbox"/> EP5.4 <input checked="" type="checkbox"/> USP <476> <input type="checkbox"/> ICH Q3C(R7) <input type="checkbox"/> Directive 2010/59/EU <input type="checkbox"/> NA
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 checked="" type="checkbox"/> EC 396/2005 <input type="checkbox"/> EP 07/2008 <input type="checkbox"/> USP<561> <input type="checkbox"/> N/A



Pesticide residual statement available	<input type="checkbox"/>
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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 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 checked="" type="checkbox"/> YES <input 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 checked="" type="checkbox"/> YES <input 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

12.Contaminants information

(according to UE regulation NO.1881/2006 and NO.629/2008 as regards maximum levels for certain contaminants in foodstuff)

●Aflatoxin B1 <5ppb ●Aflatoxins B1 + B2 + G1 + G2 <10ppb ●Ochratoxin A <15ppb	<input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" 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 and dried spices:	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA



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<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	
We confirm this product complies with NO.1881/2006 and NO.629/2008 and keep compliance statement available	<input checked="" type="checkbox"/> YES