

## Product Technical Data Sheet

Product name: Liposomal Berberine 50%

AC code: I4U04020a

1. Technical Data Sheet		
Botanical Name	Berberis aristata.	
Plant Used Part	Bark	
CAS number	633-65-8	
<p>Product Description:</p> <p>This product is using a patent-pending Dual Encapsulation Liposomal Technology (DELT), which has been proved to have better bio-availability than regular micro-encapsulation powder. There is also TEM, DLS, and Zeta potential to justify the quality.</p>		
Item	Standard	Analysis Method
Appearance & Solubility		
Appearance	The product is yellow free flowing powder with characteristic taste and odor	
Typical Analysis		
Identification	To Comply with TLC	Positive
Berberine	≥ 50%	HPLC
Loss on Drying	≤ 6.0% w/w	USP 43
Solvent Residue	USP Standard	USP
Pesticides Residue	USP Standard	USP
Particle Size	98% pass through 40 mesh	USP
Heavy metals		
Total Heavy Metals	≤ 10 ppm	AOAC 21st edition 2015.01
Lead	≤ 3.0 ppm	AOAC 21st edition 2015.01
Arsenic	≤ 1.0 ppm	AOAC 21st edition 2015.01
Cadmium	≤ 1.0 ppm	AOAC 21st edition 2015.01
Mercury	≤ 0.1 ppm	AOAC 21st edition 2015.01
Microorganism		
Total Plate Count	≤1,000 cfu/g	USP <61>
Total Molds & Yeasts	≤100 cfu/g	USP <61>
E.Coli	Negative/g	USP <61>
Salmonella	Negative/25g	USP <61>
S.Aureus	Negative/g	USP <61>
Storage & Shelf Life		
Package	25kgs/drum	
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: India or China for Berberine, liposomal made in UK

Origin statement: available

This product is a pure material <input type="checkbox"/>		This product is a compound material <input checked="" type="checkbox"/>	
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: /	
Synthetic	<input type="checkbox"/>	Starting material:	origin:
Biotechnological processing	<input type="checkbox"/> Catalysis By Enzymes	Name Of Enzyme: / Sources Of Enzymes: /	
	<input type="checkbox"/> Fermentation	Source Of Medium: / Strain: Bacteria:	
Botanical Origin	Botanical Name:	Berberis aristata.	
	Part:	Bark	
	Wild Or Cultivated:	Both	
	Country Of Origin:	China or India	
	Solvent Used:	Ethanol & Water	

### 3. Composition Statement

Berberine Extract	50%
Lecithin (GMO-Free sunflower), Modified food starch, Plant Proteins	50%

### 4. GMO declaration

	YES	NO (Means Not Contain)
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"/>

### 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 <sub>2</sub>		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 not been treated with ionising radiation	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO, not treated
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, not treated
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 not contain any nanomaterials as defined in EU food legislation	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO, does not contain
This product has not been made with nanotechnology	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO, is not made with nanotechnology
We confirm above Non-Nanomaterial statement is available	<input checked="" type="checkbox"/>	

<b>8. Residual solvents</b>		
(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: Ethanol & Ethyl Acetate                      max residual level: According to USP	<input checked="" type="checkbox"/> solvent used <input type="checkbox"/> solvent not used	
We confirm solvent residual of this product complies with:	<input checked="" type="checkbox"/> EP 7.0 <input checked="" type="checkbox"/> USP <476>	
We confirm Solvent residual statement is available	<input checked="" type="checkbox"/>	

<b>9.Pesticide residual</b>		
(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"/> EP 07/2008 <input checked="" type="checkbox"/> USP<561> <input type="checkbox"/> N/A	
Pesticide residual statement available	<input checked="" type="checkbox"/>	

<b>10.BSE/TSE information</b>		
(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 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 checked="" type="checkbox"/> EP general chapter 5.2.8
We confirm BSE/TSE statement is available	<input checked="" type="checkbox"/> YES

<b>11. Contaminants information</b>	
(according to EU Regulation No 915/2023 and NO.629/2008 as regards maximum levels for certain contaminants in foodstuff)	
<ul style="list-style-type: none"> <li>● Aflatoxin B1 &lt;5ppb</li> <li>● Aflatoxins B1 + B2 + G1 + G2 &lt;10ppb</li> <li>● Ochratoxin A &lt;15ppb</li> </ul>	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input 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 <i>and dried spices</i> : <ul style="list-style-type: none"> <li>● Maximum level of 10 µg/kg of benzo(a)pyrene</li> <li>● 50 µg/kg for the sum of PAH4 (PAH4; benzo[a]pyrene, chrysene, benz[a]anthracene and benzo[b]fluoranthene) in food supplements</li> </ul>	<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

<b>12. Others</b>
<p>We confirm we could meet with the requirement on hygiene of foodstuffs according to Reg 852/2004.</p> <p>We confirm we could meet with the requirement on general principles and requirements of food law according to REGULATION (EC) No 178/2002</p>