

PhytoTrust™ Lion's Mane Mushroom Extract

SPECIFICATION			
Product name: PhytoTrust™Lion’s Mane Mushroom Extract			
Botanical Name	Hericum erinaceus (Bull.)Per	Part	Fruit Body
Origin	China	Carrier	Maltodextrin
Source	Plant	Solvent Used	Water
Item	Standard		Analysis Method
Appearance	Brown-yellow Powder		Visual
Odor & Taste	Characteristic		Organoleptic
Typical Analysis			
Identification	Compliant with standard reference		HPLC/TLC
Assay	≥50%Polysaccharide		UV
Particle Size	98% pass 80 mesh		Sieve analysis
Residue on Ignition	≤5.0%		Ph. Eur. 2.4.16
Loss on drying	≤5.0%		Ph. Eur. 2.2.32
Bulk Density	0.4-0.6g/ml		Ph. Eur. 2.2.32
Tap Density	0.6-0.9g/ml		Ph. Eur. 2.2.32
Contaminants			
Benzo(a)pyrene	≤10µg/kg		(EU) 915/2023
PAH4	≤50µg/kg		(EU) 915/2023
Aflatoxin (Σ B1, B2, G1, G2)	< 4ppb		Ph. Eur. 2.8.18
Aflatoxin B1	< 2ppb		Ph. Eur. 2.8.18
Pesticides Residue	Conforms		EC 396/2005
Heavy metals			
Heavy metals	≤ 10ppm		ICP-MS
Lead (Pb)	≤ 3.0ppm		ICP-MS
Arsenic (As)	≤ 1.0ppm		ICP-MS
Cadmium (Cd)	≤ 1.0ppm		ICP-MS
Mercury (Hg)	≤ 0.1ppm		ICP-MS
Microorganism			
Total Bacterial Count	<1000cfu/g		Ph. Eur. 2.6.12
Total Molds Count	<100cfu/g		Ph. Eur. 2.6.12
Salmonella	Negative/25g		Ph. Eur. 2.6.13
E. coli	Negative/10g		Ph. Eur. 2.6.13
Staphylococcus aureus	Negative/10g		Ph. Eur. 2.6.13
Package	N.W. 25Kgs/fiber drum and two plastic bags inside.		
Shelf life	2 Year When Properly Stored		
Storage	Store in well-closed container at room temperature, protect from light, moisture and pest infestation.		

INGREDIENTS

An ingredient is defined in Directive 2000/13/EC on labelling: "ingredient means any substance including additives, used in the production or preparation of a foodstuff and still present in the finished product although possibly in a modified form" i.e all raw materials to produce the goods.

Please list all ingredients:

Ingredients/material composition	%	Country of origin
Lion's Mane Extract	100%	China

ORIGIN

Country of origin of the product::China					
Is a manufacturing process available		☒ YES		☐ NO	
Source of the product:		☐ Animal ☒ Plant ☐ Mineral origin ☐ Synthetic			
If animal, please answer the following questions.					
is BSE/TSE free		☐ YES		☐ NO	
Is the manufacturer registered to the European Commission		☐ YES		☐ NO	
Is the health certificate available for a food use		☐ YES		☐ NO	
If plant, please answer the following questions.					
Botanical name	Lion's Mane Extract		Geographical origin	China	
Part of the plant	Fruit Body				
Harvest method	Manual harvesting		Harvest period:	From Spring to Autumn	
Is the technical data sheet of the plant raw material available			☒ YES ☐ NO		
Are there any agents responsible for adverse effects			☐ YES ☒ NO		
If yes, please precise:					
Please precise the methods of eliminating risk constituents:					
Could you precise the treatments used on the plant harvesting?					
Irrigation	Fertilizers	Herbicides	Insecticides	Fungicides	Other
Yes	Yes	Controlled use	Controlled use	Controlled use	None

Could you precise the treatments /transformations after harvest?					
☒ Decontaminated plant(treatment used:			☐ Undecontaminated plant		
☒ Washing		☒ Drying		☐ Natural drying: ☒ Artificial drying	
Other:					
If mineral origin, please specify species					
If syntheric, please specify species					

GENETICALLY MODIFIED ORGANISMS-GMO

According to EU regulations EC/1829/2003 & EC/1830/2003

According to the EU regulations concerning the traceability and labelling of Genetically Modified Organisms (GMO), and the traceability of food products produced from GMO, we confirm that the product:

Contains ingredient(s) from Maize and/or Soya origin	☐ YES	☒ NO
Contains no material which contains, consists of or is produced from authorized GMOs in proportion higher than 0,9%. This presence is adventitious or technically unavoidable	☒ YES	☐ NO
is GMO or contains or consists of GMOs	☐ YES	☒ NO
is produced from GMOs or contains ingredients produced from GMOs	☐ YES	☒ NO
Contains ingredient(s) from other potential GMO-risk raw material(s) (rice, beet, cotton ...)	☐ YES	☒ NO
If Yes, please specify: o ingredient: o vegetable origin: o geographic origin:		
Contains no material which contains, consists of or is produced from evaluated GMOs in proportion higher than 0,5%. This presence is adventitious or technically unavoidable	☒ YES	☐ NO
For information about processing aids, is produced or contains ingredient(s) produced with GMOs or Genetically Modified Microorganisms processing aids (bacteria, yeast... or derived from GMOs or GMMs (including enzymes))	☐ YES	☒ NO
If yes, please specify:		
We confirm that the ingredient supplied is compliant in all respects with the Regulations N°1829/2003/EC and N°1830/2003/EC where applicable	☒ YES	☐ NO

SUBSTANCES OR PRODUCTS CAUSING ALLERGIES OR INTOLERANCES

According to Regulation (EU) No. 1169/2011 as regards of ingredients present in foodstuffs

Allergenic substances (Regulation EU 1169/2011 – Annex II)	Present in finished product	Present in the manufacturing site	Present on the same manufacturing line	Possible cross-contamination
Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains)	NO	NO	NO	NO
Crustaceans and products thereof	NO	NO	NO	NO
Eggs and products thereof	NO	NO	NO	NO
Fish and products thereof	NO	NO	NO	NO
Peanuts and products thereof	NO	NO	NO	NO
Soybeans and products thereof	NO	NO	NO	NO



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Milk and products thereof (including lactose)	NO	NO	NO	NO
Nuts (almond, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistachio nut, macadamia nut)	NO	NO	NO	NO
Celery and products thereof	NO	NO	NO	NO
Mustard and products thereof	NO	NO	NO	NO
Sesame seeds and products thereof	NO	NO	NO	NO
Sulphur dioxide and sulphites (>10 mg/kg or 10 mg/L expressed as SO ₂)	NO	NO	NO	NO
Lupin and products thereof	NO	NO	NO	NO
Molluscs and products thereof	NO	NO	NO	NO

NON IRRADIATION

According to UE Directive No.1999/2/CE

Has this raw material or one of its ingredients been irradiated or ionised	☐ YES	☒ NO
We confirm above non-irradiation statement is available	☒ YES	

NANOMATERIAL

According to Regulation(EU)No 1169/2011

Does this raw material contain or can be considered as engineered nanomaterial	☐ YES	☒ NO
Does this raw material have been made with nanotechnology?	☐ YES	☒ NO
Does the product contain nanotechnology as defined by the French decree no.2012-232?	☐ YES	☒ NO

RESIDUAL SOLVENTS

According to UE Directive 2009/32 modified by (UE)2010/59 and CPMP/ICH/283/95Q3C

Does the raw material contain any residual solvent	☐ YES	☒ NO
If yes, please give: percentage and name of each solvent used: level of residual solvents:		
Is the product in compliance with the UE Directive 2009/32	☒ YES	☐ NO
Is the product in compliance with the ICH guidelines	☒ YES	☐ NO

FOOD CERTIFICATE

Manufacturer's quality certificates:				
ISO 9001 ☐	HACCP ☐	ISO 14001 ☐	ISO 22000 ☐	☒ OTHER
Is the raw material Food Grade?			☒ YES	☐ NO
Can the product be used in baby food(Directive 2006/141/CE)?			☐ YES	☒ NO
Does the product comply with the UE Regulation No231/2012 about additives?			☐ YES	☒ NO
Is the product complying with a Pharmacopeia monography?			☐ YES	☒ NO



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Is the product complying with the UE Regulation No.1334/2008 about flavourings?	☐ YES	☒ NO
Was the product used in the European food industry before May 1997?	☒ YES	☐ NO
If no,could you provide an authorisation (according to Regulation 258/97/EC)?	☐ YES	☐ NO
Are stability studies available?	☒ YES	☐ NO

CONTAMINANTS

Is the product conforming to UE regulations No 2023/915 setting maximum levels for certain contaminants in foodstuffs,as amended?		☒ YES	☐ NO
Contaminants	Tested?	Result	
Pesticides (multi-residue)?	Yes	Complies with EU 396/2005	
Dioxins and dioxin like PCBs?	NO	Not routinely tested	
Heavy metals	YES	Complies (≤ 10 ppm)	
PAHs(PAH4)	YES	Complies with EU 915/2023	
Benzo[a]pyrens?	YES	Complies with EU 915/2023	
Mycotoxins (Aflatoxins, OTA)	YES	Complies with EU 915/2023	
3-MCPD	NO	Not applicable	
Doping like substances? http://list.wada-ama.org/	NO	Not applicable	

FOREIGN BODIES

Which material do you use in order to fight against the foreign bodies			
	Presence?	Test frequency	Where is it located on the process line?
Magnet	YES	Continuous	Raw material intake / processing line
Metal detector	YES	Each batch	Before packaging
Sieve	YES	Continuous	During processing
Filter	YES	Continuous	Extraction / filtration stage
X-ray detection	NO	N/A	N/A
Other(please specify)			

NUTRITIONAL VALUES

Nutritional Composition	☒ Per 100g	☐ Per serving
Energy(kJ/kcal)		
Total Fat(g)	4.2%	
Total Carbohydrate(g)		
Fibre(g)		
Protein(g)	5.0% - 27.6%	
Salt(g)		
Vitamins:		



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

TRACEABILITY

Batch size	
Batch definition	A batch is defined as a homogeneous production lot produced under the same conditions
Signification of the batch number by an example	
Marking method (labelling...)	

PACKAGING

Is the packaging material approved as food grade according to regulations 1935/2004,10/2011 and 1282/2011?	☒ YES	☐ NO
Do you guarantee the packaging traceability according to regulation 1935/2004(art 17)?	☒ YES	☐ NO
Can you guarantee that the product and its packaging supplied to do not contain Phtalates?	☒ YES	☐ NO
Can you guarantee that the product and its packaging supplied to do not contain ITX? (A packaging contaminant:Isopropylthioxanthone(ITX)found in dairy products)	☒ YES	☐ NO
Can you guarantee that the product and its packaging supplied to do not contain BisphenolA(BPA)?	☒ YES	☐ NO
Do you add desiccant bags during packaging process? If so,where do you mention it:.....	☒ YES	☐ NO
Can you provide migration test in order to guarantee packaging safety?	☒ YES	☐ NO

WASTE DISPOSAL

What is your waste disposal method?By professional waste handling facility Please indicate waste code(according to OJ 2006/1013 on July 12th,2006):

DISTRIBUTOR/MANUFACTURER CHANGE CONTROL STATEMENT OF COMMITMENT

Name of the product: : PhytoTrust™Lion' s Mane Extract

Commercial name:PhytoTrust™Lion's Mane Extract

Distributor's name

Manufacturer's name:

Manufacturing site's address:

We will notify you of any changes which may have an impact on the quality of the product,when the supplier/manufacturer informs us:

- Supplier,manufacturer or raw material origin change/
- Raw material quality change
- Manufacturing process change
- Manufacturing site change
- Equipment and/or critic premise change
- Subcontractor set up
- Subcontractor change
- Method of analysis change
- Release specifications change
- Raw material reference change
- Identification change
- Packaging unit and/or labelling and/or packaging change
- Appearance and/or content of certificate of analysis change/
- Supplying stop



Flow Chart

