



SmartHerb
Innovating Botanical Health

Address: Chengnan Road, Huaxi Subdistrict, Changxing County, Huzhou City, Zhejiang Province, 313100, China

INFINOVA® Ergothioneine-Standardized Golden Oyster Extract 1:1

SPECIFICATION			
Product name: INFINOVA® Ergothioneine-Standardized Golden Oyster Extract 1:1			
Botanical Name	Pleurotus citrinopileatus	Part	Mushroom; cultivated
Origin	China	Solvent Used	Water
Source	Plant		
Item	Standard	Analysis Method	
Appearance	Gloden Brown powder	Visual	
Odor & Taste	Characteristic	Organoleptic	
Typical Analysis			
Identification	Compliant with standard reference		HPLC/TLC
Ergothioneine	4.0 mg/g		HPLC
Particle Size	95% through 80 mesh		Sieve analysis
Moisture:	<10.0%		Ph. Eur. 2.2.32
Heavy metals			
Heavy metals	≤ 10ppm		ICP-MS
Lead (Pb)	≤ 2.0ppm		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
<i>Salmonella</i>	Negative		Ph. Eur. 2.6.13
<i>E. coli</i>	Negative		Ph. Eur. 2.6.13
<i>Staphylococcus aureus</i>	Negative		Ph. Eur. 2.6.13
Package	N.W. 25Kgs/fiber drum and two plastic bags inside.		
Shelf life	4 Year When Properly Stored		
Storage	Store in Cool Room 10-20°C in an Airtight Container		

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
INFINOVA® Ergothioneine-Standardized Golden Oyster Extract 1:1	100%	China



ORIGIN

Country of origin of the product::China					
Is a manufacturing process available	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO			
Source of the product:	<input type="checkbox"/> Animal <input type="checkbox"/> Synthetic	<input checked="" type="checkbox"/> Plant	<input type="checkbox"/> Mineral origin		
If animal, please answer the following questions.					
is BSE/TSE free	<input type="checkbox"/> YES	<input type="checkbox"/> NO			
Is the manufacturer registered to the European Commission	<input type="checkbox"/> YES	<input type="checkbox"/> NO			
Is the health certificate available for a food use	<input type="checkbox"/> YES	<input type="checkbox"/> NO			
If plant, please answer the following questions.					
Botanical name	Pleurotus citrinopileatus	Geographical origin	China		
Part of the plant	Mushroom; cultivated	Drug extract ratio	1:1		
Harvest method	Manual harvesting	Harvest period:	Spring to Autumn		
Is the technical data sheet of the plant raw material available		<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO		
Are there any agents responsible for adverse effects		<input type="checkbox"/> YES	<input checked="" type="checkbox"/> 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?					
<input checked="" type="checkbox"/> Decontaminated plant(treatment used:			<input type="checkbox"/> Undecontaminated plant		
<input checked="" type="checkbox"/> Washing	<input checked="" type="checkbox"/> Drying	<input type="checkbox"/> Natural drying:	<input checked="" type="checkbox"/> Artificial drying		
Other:					
If mineral origin, please specify species					
If syneric, 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	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
is GMO or contains or consists of GMOs	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
is produced from GMOs or contains ingredients produced from GMOs	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Contains ingredient(s) from other potential GMO-risk raw material(s)(rice, beet cotton ...)	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO



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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	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> 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))	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> 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
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



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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	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
We confirm above non-irradiation statement is available	<input checked="" type="checkbox"/> YES	

NANOMATERIAL

According to Regulation(EU)No 1169/2011

Does this raw material contain or can be considered as engineered nanomaterial	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Does this raw material have been made with nanotechnology?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Does the product contain nanotechnology as defined by the French decree no.2012-232?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> 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	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
Is the product in compliance with the ICH guidelines	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO

FOOD CERTIFICATE

Manufacturer's quality certificates:				
ISO 9001 <input type="checkbox"/>	HACCP <input type="checkbox"/>	ISO 14001 <input type="checkbox"/>	ISO 22000 <input type="checkbox"/>	<input checked="" type="checkbox"/> OTHER
Is the raw material Food Grade?			<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
Can the product be used in baby food(Directive 2006/141/CE)?			<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Does the product comply with the UE Regulation No231/2012 about additives?			<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Is the product complying with a Pharmacopeia monography?			<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Is the product complying with the UE Regulation No.1334/2008 about flavourings?			<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Was the product used in the European food industry before May 1997?			<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
If no, could you provide an authorisation (according to Regulation 258/97/EC)?			<input type="checkbox"/> YES	<input type="checkbox"/> NO
Are stability studies available?			<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO



CONTAMINANTS

Is the product conforming to UE regulations No 2023/915 setting maximum levels for certain contaminants in foodstuffs, as amended?		<input checked="" type="checkbox"/> YES	<input type="checkbox"/> 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	<input checked="" type="checkbox"/> Per 100g	<input type="checkbox"/> Per serving
Energy(kJ/kcal)		
Total Fat(g)		
Total Carbohydrate(g)	16.58% - 23.07%	
Fibre(g)		
Protein(g)	18.32% - 21.40%	
Salt(g)		
Vitamins:		
Minerals:		
Remarks: Nutrition Data are obtained by 3 rd party lab; tested on a yearly basis		

TRACEABILITY

Batch size	1MT
Batch definition	A batch is defined as a homogeneous production lot produced under the same conditions



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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?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
Do you guarantee the packaging traceability according to regulation 1935/2004(art 17)?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
Can you guarantee that the product and its packaging supplied t(do not contain Phtalates?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> 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)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
Can you guarantee that the product and its packaging supplied tos do not contain BisphenolA(BPA)?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
Do you add desiccant bags during packaging process? If so,where do you mention it:.....	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
Can you provide migration test in order to guarantee packaging safety?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> 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

<p>Name of the product: : INFINOVA® Ergothioneine-Standardized Golden Oyster Extract 1:1</p> <p>Commercial name: INFINOVA® Ergothioneine-Standardized Golden Oyster Extract 1:1</p> <p>Distributor's name</p> <p>Manufacturer's name:</p> <p>Manufacturing site's address:</p> <p>We will notify you of any changes which may have an impact on the quality of the product,when the supplier/manufacture informs us:</p> <ul style="list-style-type: none"> - 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
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Flow Chart

