

# TECHNICAL DATA

## HERBAL MELATONIN ORGANIC



ES-ECO-023-MA

RG-12.6  
Code: HRB-MLT-ORG  
Date: May. 24, 2019  
Version: v2  
Technical Department

### SPECIFICATIONS

#### HERBAL MELATONIN ORGANIC

TEST CONTENTS	SPECIFICATIONS	TESTING METHOD
<b>Botanical source</b>	<i>Medicago sativa</i> (leaves and aerial part) and <i>Chlorella vulgaris</i> (whole plant)	-
<b>Ratio</b>	100:1	-
<b>Description</b>	Dark green-tan to dark brown powder, with characteristic odor and taste	Organoleptic
<b>Assay (Natural Melatonin)</b>	10.0mg/g (+/- 10%)	HPLC (USP)
<b>Solubility</b>	Dispersible in water	Visual
<b>Particle size</b>	≥90% through 500micron sieve	Sieve screening
<b>Moisture</b>	<10.0%	AOAC
<b>MICROBIOLOGY (control plan)</b>		
<b>Total plate count (cfu/g)</b>	<50000cfu/g	EP
<b>Yeast and Molds (cfu/g)</b>	<500cfu/g	EP
<b>Enterobacteria (cfu/g)</b>	<100cfu/g	EP
<b>Escherichia coli</b>	Negative/1g	EP
<b>Salmonella</b>	Negative/25g	EP
<b>HEAVY METALS (control plan)</b>		
<b>Pb (ppm)</b>	<3.0 ppm	ICP-MASS
<b>Cd (ppm)</b>	<1.0 ppm	ICP-MASS
<b>Hg (ppm)</b>	<0.1 ppm	ICP-MASS
<b>OTHERS</b>		
<b>SHELF LIFE</b>	No less than three years when properly store	
<b>STORAGE</b>	Store in a cool dry area. Do not freeze. Keep away from strong, direct light	
<b>PACKAGING</b>	10kg	
<b>COUNTRY OF ORIGIN</b>	Australia	

We thank you to take note of these documents. Without any news from you within 5 days after reception, these enclosed documents will be considered as accepted.

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### ALLERGEN DECLARATION EU

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	DIRECT INCORPORATION		CROSS CONTAMINATION					
			Presence on the production line		Presence on the production workshop		Presence on the production factory	
	YES	NO	YES	NO	YES	NO	YES	NO
Cereals containing gluten(1) and products thereof		No		No		No		No
Crustaceans and products thereof		No		No		No		No
Eggs and products thereof		No		No		No		No
Fish and products thereof (2)		No		No		No		No
Peanuts and products thereof		No		No		No		No
Soybeans and products thereof (3)		No		No		No	Yes*	Yes
Milk and products thereof (including lactose)(4)		No		No		No		No
Nuts (5) or products thereof		No		No		No		No
Celery and products thereof		No		No		No		No
Mustard and products thereof		No		No		No		No
Sesame seeds and product thereof		No		No		No		No
Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10 mg/l expressed as SO <sub>2</sub>		No		No		No		No
Lupines and products thereof		No		No		No	Yes*	
Mollusc and product thereof		No		No		No		No

- (1) Cereals which contain gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridized 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 gelatin used as carrier for vitamin or carotenoid preparations, fish gelatin 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

\*The manufacturer guarantees an allergen-free finished product.

In accordance with the directive 1169/2011EC

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### GMO DECLARATION

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	Present(yes/no)	GM-origin (yes/no)
Cotton	No	Not Applicable
Maize	No	Not Applicable
Potato	No	Not Applicable
Rape	No	Not Applicable
Soya	No	Not Applicable
SugarBeet	No	Not Applicable
Tomato	No	Not Applicable
Wheat	No	Not Applicable

The following ingredients produced from genetically modified organisms are present in the product: **None**

*In accordance with the regulation (EC) No.1829/2003 and (EC) No.1830/2003 of the European Parliament*

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### STATEMENTS

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### Non IRRADIATION/NON IONIZED Statement

We hereby certify that the product has not been sterilized by ionizing radiation at any point during the entire manufacturing process and therefore is in full compliance with the relevant legislated regulations (Directive 1999/2/CE)

### BSE/TSE Statement

We hereby certify that 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) and it is conform to the EU legislation 999/2001

### PACKAGING Statement

We hereby certify that the packing used is in compliance with  
-Commission Regulation (EC)No 1935/2004 and Regulation (EU) No 10/2011  
Regarding packaging materials and articles intended to come into contact with food.

### PESTICIDE Statement

We hereby certify, basis on our actual knowledge of production process, raw materials and equipment used in the above mentioned product comply with the European legislation on pesticide residues used in Organic Agriculture, esp. Regulation (EC)834/2007 and subsequent modifications.

### RESIDUAL SOLVENT Statement

We hereby certify that the product meets with:  
Directive E 2010/59/EU of 26 August 2010 amending Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.

### CONTAMINANT Statement

This is to certify that the product meets with:  
- REGULATION (EC) No. 1881/2006 and subsequent amendments as concerns the maximum level admitted of the following contaminants:  
- Aflatoxin B1  
- Aflatoxins B1 + B2 + G1 + G2  
- Ochratoxin  
- Melamine  
  
- REGULATION (EC) No. 1933/2015 amending regulation (EC) No. 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons, in particular:  
- Maximum level of 10 µg/kg of benzo(a)pyrene  
- 50 µg/kg for the sum of PAH4 (benzo(a)pyrene, chrysene, benz[a]anthracene and benzo[b]fluoranthene) in food supplements

### NANOMATERIAL Statement

According to the definition of "nanomaterials" of the EU Regulation (EU) No. 1169/2011 of the European parliament and of the council of 25 October 2011 on the provision of food information to consumers, we hereby attest that no nanomaterials are used in the formulation or in the packaging material of the product.

### ANTI-DOPING Statement

As per the list of 2017 and subsequent amendments of the world anti-doping agency, the ingredient is not a doping substance and not a combination of doping substances. The ingredient does not contain any doping substance. The ingredient does not result from a doping substance.

### EXPECTED USAGE

The expected usage of this product is its incorporation as an ingredient in the food industry or the pharmaceutical industry.