

Technical Data Sheet

Product Name: Melatonin 2.5% Prolonged-Release Matrix Blend **Trade Brand:** Smart Herb

Technical Data Sheet			
AC Code	SH07020	CAS number	N/A
Molecular formula	N/A	Molecular weight	N/A
Origin	China	Source	Chemical synthesis
Solvent Used	N/A		
Item	Standard	Analysis Method	
Appearance	White to off-white free-flowing uniform powder	Visual	
Typical Analysis			
Particle Size	95% pass 80 mesh	Sieve analysis	
Bulk Density	0.60–0.75 g/mL	Ph. Eur. 2.9.34	
Residue on Ignition	≤1.0%	Ph. Eur. 2.4.16	
Loss on drying	≤2.0%	Ph. Eur. 2.2.32	
Assay (Melatonin)	90.0% – 110.0% of label (2.5%)	HPLC	
Single Unknown Impurity	≤0.10%	HPLC	
Total Impurities	≤0.50%	HPLC	
Serotonin (5-HT)	≤100 ppm (Strict BfArM limit)	HPLC	
Residual solvents			
Methanol	≤0.3%	HPLC	
Contaminants			
Triadimenol	≤0.01 mg/kg	EN 15662:2018	
Chlorantraniliprole	≤0.01 mg/kg	EN 15662:2018	
Indoxacarb	≤0.01 mg/kg	EN 15662:2018	
Bifenthrin	≤0.01 mg/kg	EN 15662:2018	
Benzo(a)pyrene	≤2.0 µg/kg	(EU) 915/2023	
PAH4	≤10 µg/kg	(EU) 915/2023	
Aflatoxin (Σ B1, B2, G1, G2)	≤4.0 µg/kg	Ph. Eur. 2.8.18	
Aflatoxin B1	≤2.0 µg/kg	Ph. Eur. 2.8.18	
Heavy metals			
Lead (Pb)	≤0.5 ppm,	ICP-MS	
Arsenic (As)	≤1.5 ppm,	ICP-MS	
Cadmium (Cd)	≤0.5 ppm,	ICP-MS	
Mercury (Hg)	≤0.1 ppm	ICP-MS	
Microorganism			
Total Bacterial Count	≤1000 CFU/g	Ph. Eur. 2.6.12	
Total Molds Count	≤100 CFU/g	Ph. Eur. 2.6.12	
Salmonella	Negative	Ph. Eur. 2.6.13	
E. coli	Negative	Ph. Eur. 2.6.13	
Staphylococcus aureus	Negative	Ph. Eur. 2.6.13	
Paeruginosa	Negative	Ph. Eur. 2.6.13	
Package	25kg/drum		
Shelf life	24 months		
Storage	Sealed, dry, < 25°C, RH < 60%, keep away from light		

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
Melatonin API	2.5%	China
HPMC K15M CR	34.0%	China
MCC PH102	62.5%	China
Magnesium Stearate	1.0%	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 ☐ Biotechnological processing		
please answer the following questions.			
Starting material:	Synthetic raw materials for Melatonin API	Origin:	China
Starting material:	Pharmaceutical excipients (HPMC, MCC, Magnesium Stearate)	Origin:	China

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	☐ YES	☒ NO



SmartHerb

Innovating Botanical Health

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than 0,5%. This presence is adventitious or technically unavoidable		
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
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 asengineered 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

WADA Anti-Doping Statement

Current WADA Prohibited List

Does the product contain any prohibited substances (hormones, anabolic agents, stimulants) listed on WADA Prohibited List?	☐ YES	☒ NO
Is there any risk of cross-contamination with WADA banned substances during production?	☐ 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: Methanol level of residual solvents:≤ 3000 ppm (0.3%),		
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	
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
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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?	YES	Complies with EU 915/2023	
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	NO	Continuous	Extraction / filtration stage
X-ray detection	NO	Not applicable	Not applicable
Other(please specify)	NO	Not applicable	Not applicable

NUTRITIONAL VALUES

Nutritional Composition	☒ Per 100g	☐ Per serving
Energy(kJ/kcal)	310 kcal	
Total Fat(g)	0.8	
Total Carbohydrate(g)	93.2	
Fibre(g)	86.5	
Protein(g)	0	
Salt(g)	0.02	
Vitamins:	N/A	
Minerals:	0.25	
Remarks: 200 mg of this 2.5% blend provides 3 mg melatonin per tablet		

TRACEABILITY

Batch size	500kg
Batch definition	A batch is defined as a homogeneous production lot produced under the

	same conditions
Signification of the batch number by an example	N/A
Marking method (labelling...)	N/A
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 t(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 tos 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

Material Safety Data Sheet

Section 1 Identification of Substance			
Product Name:	Melatonin 2.5% Prolonged-Release Matrix Blend	CAS No.	N/A
Molecular Formula:	N/A	Molecular Weight:	N/A
Section 2 Hazards Identification 2.1 Classification according to Regulation (EC) No 1272/2008 (CLP) This mixture is NOT CLASSIFIED as hazardous under EU CLP regulation. No hazard classes applicable. 2.2 Label elements No hazard label, no signal word, no hazard statements, no precautionary statements required. 2.3 Other hazards No PBT, vPvB, endocrine disrupting or other hazardous properties under REACH.			
Section 3 Composition, Information on Ingredients 3.1 Melatonin (CAS 73-31-4): 2.5% — No hazardous classification under EU CLP 3.2 Microcrystalline Cellulose (MCC): 62.5% — Non-hazardous 3.3 Hypromellose (HPMC): 34.0% — Non-hazardous 3.4 Magnesium Stearate: 1.0% — Non-hazardous			
Section 4 First Aid Measures 4.1 Inhalation: Remove to fresh air. If coughing or discomfort persists, seek medical advice. 4.2 Skin contact: Wash thoroughly with clean water and soap. 4.3 Eye contact: Flush continuously with plenty of clean water for 10 - 15 minutes. 4.4 Ingestion: No specific risk in small quantity; seek medical help if large intake occurs.			

Section 5 Fire-Fighting Measures

- 5.1 Suitable extinguishing media: Water mist, dry powder, CO₂, foam.
- 5.2 Fire hazards: Combustion produces CO₂, CO and nitrogen oxide fumes.
- 5.3 Firefighter protection: Wear full protective clothing and breathing apparatus.

Section 6 Accidental Release Measures

- 6.1 Personal precaution: Wear dust mask and gloves, avoid dust inhalation.
- 6.2 Environmental precaution: Prevent leakage into sewer, soil and surface water.
- 6.3 Clean-up method: Collect powder with clean tools, place into sealed containers; clean residue with damp cloth.

Section 7 Handling and Storage

- 7.1 Handling: Operate under ventilation, avoid dust generation, no eating or smoking during operation.
- 7.2 Storage: Store in cool, dry, dark warehouse (15 – 25° C), sealed packaging, away from oxidants and direct sunlight.

Section 8 Exposure Controls/Personal Protection

- 8.1 Engineering controls: Local dust exhaust ventilation system.
- 8.2 Respiratory protection: Disposable dust mask.
- 8.3 Eye protection: Safety goggles.
- 8.4 Hand protection: Nitrile protective gloves.

Section 9 Physical and Chemical Properties

Appearance: White to off-white free-flowing uniform powder

Section 10 Stability and Reactivity

- 10.1 Stability: Stable under normal storage and handling conditions.
- 10.2 Incompatible substances: Strong oxidizing agents, strong acids.
- 10.3 Hazardous decomposition: No dangerous polymerization; thermal decomposition produces nitrogen oxides.

Section 11 Toxicological Information

- 11.1 Acute toxicity: Low toxicity; Melatonin oral LD₅₀ >3200 mg/kg (rat).
- 11.2 Reproductive toxicity: No reproductive toxicity classification applies. No adverse reproductive risks under normal food-grade handling and usage.
- 11.3 Irritation: Minor mechanical dust irritation may occur from powder dust; no chemical corrosion or toxic irritation.

Section 12 Ecological Information

Low ecotoxicity, no bioaccumulation. Cellulose excipients are biodegradable. No PBT/vPvB substances contained.

Section 13 Disposal Considerations

Dispose waste material via licensed professional waste disposal institution in accordance with EU 2008/98 waste directive. Do not discard randomly.

Section 14 Transport Information

- 14.1 UN Number: None
- 14.2 Transport classification: NON-DANGEROUS GOODS
- 14.3 Transport requirement: Sealed, moisture-proof, avoid extrusion and sunlight.

Section 15 Regulatory Information

Compliant with EU REACH 1907/2006, CLP 1272/2008, EU 396/2005, EU 2023/915 food contaminant regulations and food supplement safety standards.

Section 16 Other Information

Product is exclusively for food supplement raw material use.



Flow Chart

