



## Ashwagandha

SPECIFICATION			
Product name: Ashwagandha 5.0% HPLC			
Botanical Name	Withania somnifera	Part	Roots and Aerial Parts
Origin	India	Solvent Used	Water&Ethanol
Source	Plant		
<b>Item</b>	<b>Standard</b>	<b>Analysis Method</b>	
Appearance	Yellow Tan to Brown Powder	Visual	
Odor & Taste	Characteristic	Organoleptic	
<b>Typical Analysis</b>			
Identification	Compliant with standard reference	HPLC/TLC	
Total Withanolides	≥5.0%	HPLC	
Particle Size	95% through 40 mesh	Sieve analysis	
Loss on drying	≤5.0%	Ph. Eur. 2.2.32	
<b>Residual solvents</b>			
Ethanol	≤ 5000ppm	GC	
<b>Pesticide Residues</b>			
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	
<b>Heavy metals</b>			
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	
<b>Microorganism</b>			
Total Bacterial Count	<10,000cfu/g	Ph. Eur. 2.6.12	
Total Molds Count	<1,000cfu/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	
Package	N.W. 25Kgs/fiber drum and two plastic bags inside.		
Shelf life	2 Year When Properly Stored		
Storage	Store in a well-closed container Away from moisture,light, oxygen.		

## 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
Ashwagandha	100%	India

## 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 checked="" type="checkbox"/> Plant	<input type="checkbox"/> Mineral origin <input type="checkbox"/> Synthetic		
<b>If animal, please answer the following questions.</b>					
is BSE/TSE free	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO			
Is the manufacturer registered to the European Commission	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO			
Is the health certificate available for a food use	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO			
<b>If plant, please answer the following questions.</b>					
Botanical name	Withania somnifera	Geographical origin	India		
Part of the plant	Roots and Aerial Parts				
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:					
<b>Could you precise the treatments used on the plant harvesting?</b>					
Irrigation	Fertilizers	Herbicides	Insecticides	Fungicides	Other
Yes	Yes	Controlled use	Controlled use	Controlled use	None

<b>Could you precise the treatments /transformations after harvest?</b>			
<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:			
<b>If mineral origin, please specify species</b>			
<b>If synerhic, please specify species</b>			

## 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
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
Sesame seeds and products thereof	NO	NO	NO	NO



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Sulphur dioxide and sulphites (>10 mg/kg or 10 mg/L expressed as SO <sub>2</sub> )	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 asengineered 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 checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
If yes,please give: percentage and name of each solvent used: Water & Ethanol level of residual solvents: Ethanol<5000ppm		
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	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
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for certain contaminants in foodstuffs,as amended?		
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 ( $\leq 10$ 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? <a href="http://list.wada-ama.org/">http://list.wada-ama.org/</a>	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)	/	
Fibre(g)	/	
Protein(g)	/	
Salt(g)	/	
Vitamins:	/	
Minerals:	/	
Remarks: Nutrition Data are obtained by 3 <sup>rd</sup> 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
Signification of the batch number by an example	
Marking method (labelling...)	



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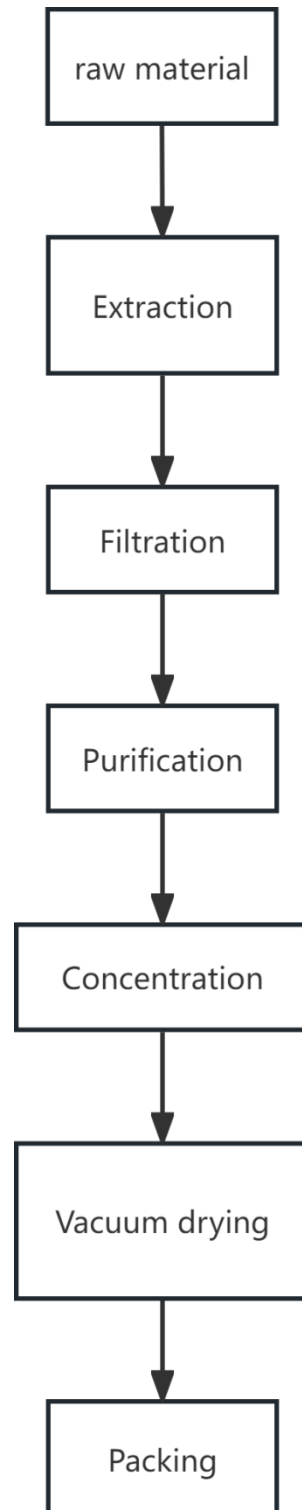
<b>PACKAGING</b>	
Is the packaging material approved as food grade according to regulations 1935/2004,10/2011 and 1282/2011?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
Do you guarantee the packaging traceability according to regulation 1935/2004(art 17)?	<input checked="" type="checkbox"/> 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
<b>WASTE DISPOSAL</b>	
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 : Ashwagandha Extract
Commercial name: Ashwagandha Extract
Distributor's name
Manufacturer's name:
Manufacturing site's address:
<p>We will notify you of any changes which may have an impact on the quality of the product,when the supplier/manufacturer informs us:</p> <ul style="list-style-type: none"> <li>Supplier,manufacturer or raw material origin change/</li> <li>- Raw material quality change</li> <li>- Manufacturing process change</li> <li>Manufacturing site change</li> <li>Equipment and/or critic premise change</li> <li>Subcontractor set up</li> <li>Subcontractor change</li> <li>Method of analysis change</li> <li>Release specifications change</li> <li>Raw material reference change</li> <li>Identification change</li> <li>Packaging unit and/or labelling and/or packaging change</li> <li>Appearance and/or content of certificate of analysis change/</li> <li>Supplying stop</li> </ul>



## Flow Chart



# MATERIAL SAFETY DATA SHEET

## Ashwagandha 5.0% HPLC

### 1. PRODUCT AND COMPANY IDENTIFICATION

**Product identifier**

**Product name:** Ashwagandha Extract

**Any restrictions on use:** No additional information available.

### 2. HAZARDS IDENTIFICATION

**Classification of the substance or mixture:** Not classified.

**Hazard pictograms or symbols:** No data available.

**Signal word:** No data available.

**Hazard statement(s):** Small amount: None known. Large mount: Exposure **may produce an allergic reaction.**

**Precautionary statement(s):** Avoiding exposure and leakage.

**Other hazards not otherwise classified:** No data available.

### 3. COMPOSITION/ INFORMATION ON INGREDIENTS

Chemical name	CAS#	Exact percentage	Hazard class and category	Concentration limits
Ashwagandha Extract	NA	100%	Not classified.	No data available.

### 4. FIRST AID MEASURES

**Route(s) of Entry:** Inhalation? Yes Skin? Yes Eyes? Yes Ingestion? Yes Other: Injection

**After inhaled**

Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

**After swallowed**

Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

**First aid measures**

**After skin contact**

Immediately wash skin with soap and plenty of water. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

**After eye contact**

Hold eyelids apart and flush eyes with plenty of water. After initial flushings, remove any contact lenses and continue flushing for at least 20 minutes. Have eyes examined and tested by medical personnel.

## 5. FIRE FIGHTING MEASURES

### Extinguishing Media:

Alcohol foam, carbon dioxide, or water spray when fighting fires involving this material.

### Unsuitable Extinguishing Media:

No data available.

### Fire Fighting Instructions:

As in any fire, wear self-contained breathing apparatus pressure-demand (MSHA/NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions and protective equipment and emergency procedure:

Wear a NIOSH/MSHA approved self-contained breathing apparatus and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

### Methods and material for containment and cleanup:

Vacuum or sweep up material and place in disposal container.

Avoid raising dust. After removal, ventilate contaminated area and flush thoroughly with water.

### Environmental precautions:

Keep away from drains, surface and ground water.

## 7. HANDLING AND STORAGE

### Precautions for safe Handling:

Avoid breathing (dust, vapor, mist, gas).

Avoid contact with eyes, skin, and clothing.

Avoid prolonged or repeated exposure.

Do not reuse this container.

Use with adequate ventilation.

Wash thoroughly after handling.

### Condition for safe storage:

Store in tight, light-resistant containers, avoid exposure to direct sunlight, moisture and excessive heat.

Specific end use(s):

No data available.



## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Exposure:

OSHA PEL No data. ACGIH TLV No data. Other exposure limit No data.

### Protective Equipment:

Eye wash station in work area

Lab coat

Latex disposable gloves Safety glasses

Safety shower in work area

Vent Hood

### Respiratory Equipment (Specify Type):

No data available.

### Eye Protection:

Safety glasses

### Protective Gloves:

Latex disposable gloves

### Other Protective Clothing:

Lab coat

### Engineering Controls (Ventilation etc.):

Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical States:**  Gas  Liquid  Solid

**Melting Point:** No data available.

**Boiling Point:** No data available.

**Autoignition Pt:** No data available.

**Flash Pt:** No data available.

**Explosive Limits:** LEL: No data available. UEL: No data available.

**Specific Gravity (Water = 1):** No data available.

**Vapor Pressure (vs. Air or mm Hg):** No data available.

**Vapor Density (vs. Air = 1):** No data available.

**Evaporation Rate (vs Butyl Acetate=1):** No data available.

**Relative density:** No data available.

**Solubility in Water:** Dissolve in water

**Partition coefficient:** No data available.

**Auto-ignition temperature:** No data available.

**Viscosity:** No data available.

**Decomposition temperature:** No data available.

**pH:** No data available.

**Appearance and Odor:** Reddish Brown Fine Powder Characteristic Odor



## 10. STABILITY AND REACTIVITY

**Reactivity:** Stable under the normal condition.

**Chemical Stability:** Unstable [ ] Stable [  ]

**Possibility of Hazardous Reactions:** No data available.

**Conditions To Avoid Instability:** Protect from moisture

**Incompatible Materials:** Strong oxidizing agents

**Hazardous Decomposition product Or Byproducts:** No data available.

**Hazardous Polymerization:** Will occur [ ] Will not occur [  ]

## 11. TOXICOLOGICAL INFORMATION

### Routes of exposure:

Inhalation? Yes

Skin? Yes

Eyes? Yes

Ingestion? Yes

Other: Injection

### Toxicological Information:

The toxicological effects of this compound have not been thoroughly studied.

### Carcinogenicity:

NTP? No IARC Monographs? No OSHA Regulated? No

## 12. ECOLOGICAL INFORMATION

**Toxicity:** No data available.

**Persistence and Degradability:** No data available.

**Bioaccumulative potential:** No data available.

**Mobility in soil:** No data available.

**Results of PBT and vPVB assessment:** No data available.

**Other Adverse Effects:** Runoff from fire control or dilution water may cause pollution.

## 13. DISPOSAL CONSIDERATIONS

**Waste Disposal Method:** Dispose in accordance with local, state and federal regulations.

## 14. TRANSPORT INFORMATION

**UN number:** No dangerous good in sense of transport regulation.

**UN Proper Shipping Name:** No data available.

**Transport Hazard Class(es):** No data available.

**Packing Group:** No data available.

**Environmental hazards:** No data available.

**Special Precautions for User:** No data available.

**Transport in Bulk:** No data available.

## 15. REGULATORY INFORMATION

**US OSHA:** No

**EU regulation:** No

**National regulation:** No

**Chemical safety assessment:** No data available.

## 16. OTHER INFORMATION

### **Company Policy or Disclaimer:**

**DISCLAIMER:** This information is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purpose