

GENERAL SPECIFICATION

Ashwagandha extract powder (1,5% withanolides)

ASEP15

General Information			
Productcode	ASEP15	Quality assurance:	NORMAL
Batch code	AM...		
Best before		
Substance	Ashwagandha extract powder (1,5% withanolides)		
Species / Chemical name	Withania somnifera		
Plant parts used / Identification	Roots		
Appearance	Light brown to brown powder		
Flavor / Aroma	Characteristic odor, bitter taste	<i>Taric custom code:</i> 1302.1970.00	
Country of Origin	India		

Analyses	Test method	Specification	Results
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Composition specification			
Assay (on dry basis)	HPLC	≥ 1,5% withanolides	
Extraction ratio		± 5 : 1	
Extraction method		solvent extraction	
Extraction medium		ethanol/water	
Identification	TLC	positive by TLC	

Physical Property			
Loss on drying (105°C)	USP<731>	≤ 5%	
Total ash	USP	≤ 10%	
Bulk density (tapped)	USP<616>	0,4 - 1,0 g/ml	
Particle size	sieve	100% through 60 mesh	

Chemical Property			
Heavy metals	USP<231>	≤ 10 ppm	
Lead (Pb)	ICP-MS	≤ 3 ppm	
Arsenic (As)	ICP-MS	≤ 2 ppm	
Cadmium (Cd)	ICP-MS	≤ 1 ppm	
Mercury (Hg)	ICP-MS	≤ 0,1 ppm	
PAH's:	sum 4 PAH's	≤ 50 ppb	
	benzo(a)pyrene	≤ 10 ppb	
Pesticide residues		Conform Reg. 396/2005 CE	
Residual solvents (ethanol)		Conform Dir. EC 32/2009	

Microbiological Tests			
Total Plate Count	AOAC	≤ 10.000 cfu/g	
Yeast & Mold	AOAC	≤ 1.000 cfu/g	
E.Coli	AOAC	Negative	
Salmonella	AOAC	Negative	

Typical nutritional values (per 100 grams)			
Energy (kJ)	?	Total proteins (%)	?
Total carbohydrates (%)	?	Sugar (%)	?
Fat (%)	?	Dietary fibers (%)	?
Saturated Fat (%)	?	Sodium (%)	?

Directions for use	See: https://www.benseng.com/product/product-ashwaganda-en.php
Statement	Allergens free according Regulation (EU) N° 1169/2011. Non-GMO. Not irradiated. Pah's and pesticides only controlled by random re-testing. Manufacturer is FSSC 22000, HACCP, GMP and ISO9001-2015 certified by SGS United Kingdom Ltd.
Storage	Store in a cool dry place in well closed original package
Shelf Life	At least 3 years when stored properly.
Standard packaging	Food grade polyethylene bags in cardboard box or drum

cfu= colony forming units

ppm= parts per million

ppb= parts per billion

n.d. = not detectable

As stated by our supplier

The manufacturer/supplier of this product or ingredient is carefully selected according HACCP-principles. Nevertheless this data is purely informative and does not absolve you of the need to check the goods for (specific) use yourself. You remain fully and at all times responsible for the product, the purpose for or in which it is used and the possible consequences in which it can result. Under no circumstances Benseng International BV can be held responsible for the application of it's products in violation with existing regulations and/or licenses. Except per contractual agreement, this data sheet is subject to change without prior notice. Benseng International BV's policy is to prevent any genetic modification of it's products or their ingredients.

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STATEMENTS

Ashwagandha extract powder (1,5% withanolides)

NANOMATERIAL

This product does not contain nanomaterials as defined by Regulation (EC) N° 1169/2011.

NON IRRADIATION

This raw material or one of its ingredients has not been irradiated or ionised according to Directive N° 1999/2/CE.

BSE-TSE

This product is BSE/TSE free according regulation (CE) 220/2009.

GENETICALLY MODIFIED ORGANISMS – GMO

This ingredient is compliant in all respects with the Regulations N° 1829/2003/EC and N° 1830/2003/EC where applicable.

ALLERGENS

This ingredient does not contain any of the 14 substances causing allergies or intolerances according Regulation (EU) N° 1169/2011 and therefore no substances of this list have to be mentioned on the label according Directive 2000/13/EC, Directive 2003/89/EC, Directive 2005/26/EC, Directive 2006/142/EC and Directive 2007/68/EC. However, the Leda-list contains in addition to the 14 legal allergens 10 more additional allergens. One of this additional substances: "Maize and products thereof" is present in this product, but it is not mandatory to mention these additional allergens on the label.

PRODUCT SOURCE

This ingredient is manufactured from herbal material, so has vegetable origin.

No animal containing ingredients are used in any part of the manufacturing process according Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

VEGETARIANS/VEGANS:

This product is suitable for Vegetarians, because: "it is free of all animals and fish products and derivatives thereof, except maybe for honey, egg, milk and milk products". It is also suitable for Vegans, because: "no products are issued from animals, including honey, egg, milk, and milk products".

ANIMAL TESTING

This product has not been the subject of animal testing according EU Cosmetic Regulation (EC/1223/2009) . Known toxicity studies on animals might have been carried out by others before Regulation EC/1223/2009 came into action or outside the region of this Regulation's influence.

KOSHER / HALAL

This product is Kosher and Halal certified.

PACKAGING

The original packaging material is approved as food grade according (EC) regulation 1935/2004, 10/2011 and 1282/2011.

HAZARDS IDENTIFICATION

- Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008

- Label elements

The product does not need to be labelled in accordance with Regulation (EC) No 1272/2008 [CLP].

IMPORT & EXPORT

This substance is not listed in the Annex I of Dangerous Chemicals (Regulation (EC) No 649/2012).

RISK ASSESSMENT

This substance is not listed in a priority list (as foreseen under Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances.).

DOPING LIST

To the best of our knowledge, this product does not contain, nor is it contaminated with substances on the current World Anti-Doping Agency (WADA) Prohibited substances list.

The information above 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 purposes. In no event shall supplier be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if supplier has been advised of the possibility of such damages.

ALLERGENS DECLARATION

Ashwagandha extract powder (1,5% withanolides)

SUBSTANCES OR PRODUCTS CAUSING ALLERGIES OR INTOLERANCES

According Regulation (EU) N° 1169/2011 as regards indication of ingredients present in foodstuffs

The modification of the 2000/13 European directive about the labelling aims at the obligation of labelling clearly the allergen below used in food products production and still present in the product, even in a modified form, including additives and processing aids.

Please indicate Cross contamination only if for any reason can be possible

Allergens	Absent	Present	Cross
Azo colours	X		
Beef	X		
Benzoic acid (from E210 to E213)	X		
BHA-BHT (E320-E321)	X		
Celery and products thereof	X		
Chicken (meat)	X		
Cinnamon	X		
Cocoa	X		
Coriander	X		
Crustaceans and products thereof	X		
Eggs and products thereof	X		
Fish and products thereof	X		
Fructose	X		
Gelatin	X		
Glutamate added (from E620 to E625)	X		
Gluten (<20ppm)	X		
Legumes/Pulses	X		
Lupin and products thereof	X		
Maize and products thereof *)		X	
Milk protein (<0.1%)	X		
Milk sugar (lactose) (<0.02%)	X		
Molluscus and products thereof	X		
Mustard and products thereof	X		
Nuts: almonds (<i>Amygdalus communis</i> L.), Hazelnut (<i>Corylus avellana</i>), Walnut (<i>Juglans regia</i>), Cashew (<i>Anacardium occidentale</i>), Pecan Nut (<i>Carya illinoensis</i> (Wangenh.)K.Koch), Brazil nut (<i>Bertholletia excelsa</i>), Pistacchio nut (<i>Pistacia vera</i>), Macadamia nut and queensland nut (<i>Macadamia ternifolia</i>) and products thereof	X		
Peanuts and products thereof	X		
Pork	X		
Rye	X		
Sesame seeds and products thereof	X		
Sorbic acid (E200-E203)	X		
Soyabeans and products thereof	X		
Sucrose	X		
Sulphite (from E220 to E228) <10 mg/kg or mg/L expressed as SO ₂	X		
Tartrazine (E102)	X		
Umbelliferae	X		
Vanillin	X		
Wheat	X		
Yeast	X		

Remarks: *) Contains Maltodextrine made from maize as excipient.

Disclaimer: The information set out in this Specifications and/or in any other document provided with the products does not constitute any warranty other than conformity to the current product specifications. Any relevant legislation governing the use of the product should be observed by the User to ensure that the use of the products and any labelling is in compliance with any local or national legislation, regulation or standard. All other warranties, express or implied are hereby explicitly excluded.

As stated by our supplier

ETHYLENE OXIDE (ETO) STATEMENT

Ashwagandha extract powder (1,5% withanolides)

To whom it may concern:

This letter is to certify that Ethylene Oxide is not used to sterilize any product and equipment used in the manufacturing of:

Ashwagandha extract powder (1,5% withanolides)

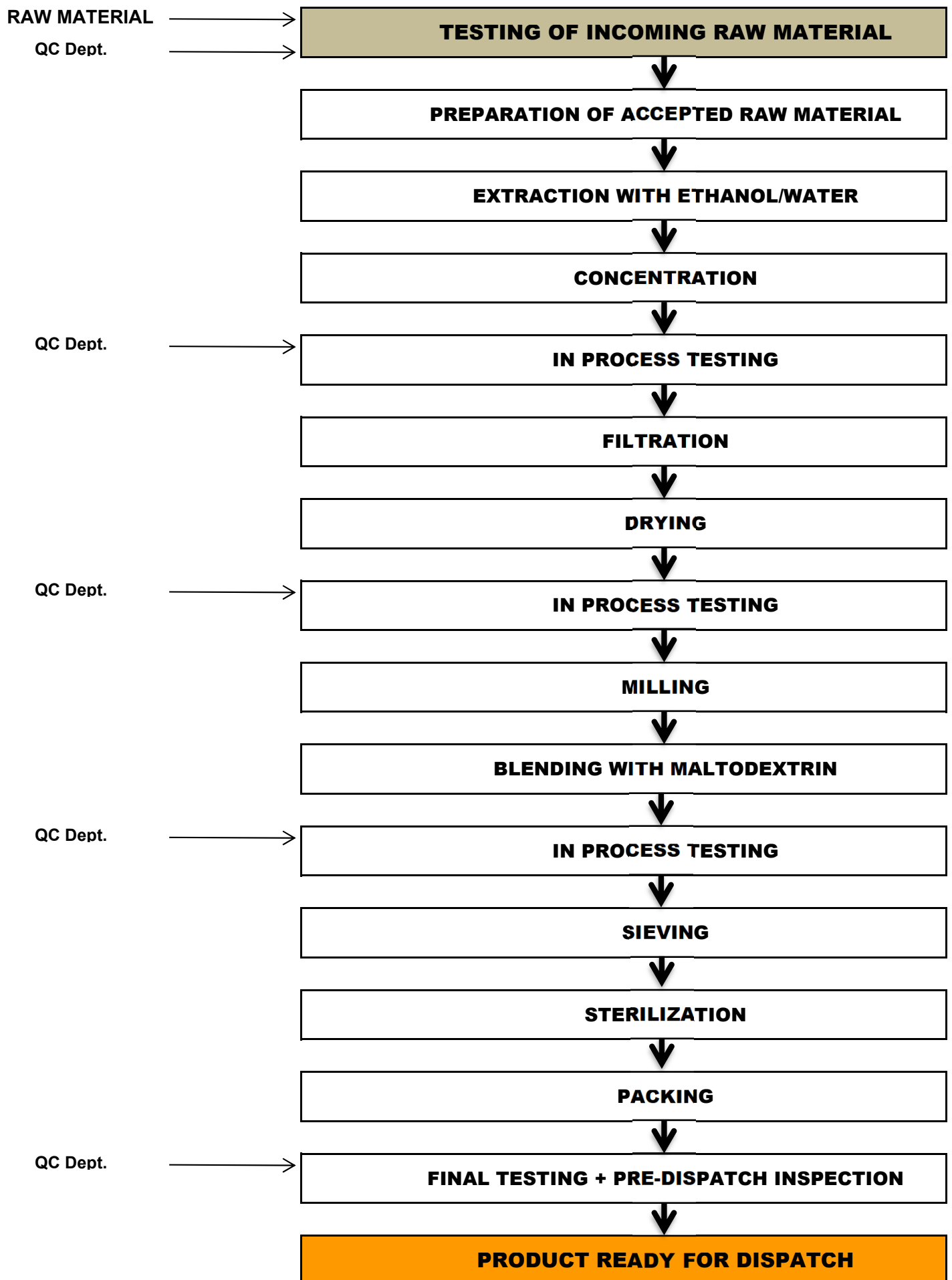
by manufacturer of this material.

Disclaimer: The information set out in this Specifications and/or in any other document provided with the products does not constitute any warranty other than conformity to the current product specifications. Any relevant legislation governing the use of the product should be observed by the User to ensure that the use of the products and any labelling is in compliance with any local or national legislation, regulation or standard. All other warranties, express or implied are hereby explicitly excluded.

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MANUFACTURING PROCESS FLOWCHART

Ashwagandha extract powder (1,5% withanolides)



As stated by our supplier

MATERIAL SAFETY DATA SHEET (MSDS)

Ashwagandha extract powder (1,5% withanolides)

1 Identification of the substance/mixture and of the company/undertaking

1.1 Product name: Ashwagandha extract powder	1.2 Supplier of MSDS:
CAS Number : 90147-43-6	Benseng International BV
ESIS EC# (EINECS) : 290-434-9	Rietven 157
Synonyms: Ajagandha, Indian ginseng, Winter cherry	5464 PJ Veghel, The Netherlands
Chemical name: Withania somnifera, ext.	Emergency phone:
Chemical formula: not applicable	+31-413-355361
1.3 REACH:	A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.
1.4 Proposed uses:	Food, food supplements, further processing. Check for legal status the appropriate authorities in country of intended use.

2 Hazards identification

- 2.1 Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008
- The substance is not classified according to the CLP regulation.
- Storage: Cool and dry in well-closed original packaging
- 2.2 Label elements:
- The product does not need to be labelled in accordance with Regulation (EC) No 1272/2008 [CLP].
- Other hazards: not available.
 - Results of PBT and vPvB assessment
 - PBT: Not applicable.
 - vPvB: Not applicable.

3 Composition/information on ingredients

3.1 Composition:

Name	CAS#	% by Weight
Ashwagandha extract powder	90147-43-6	100%

- 3.2 Toxicological Data on Ingredients:
- In acute toxicity studies the LD50 of a Withania somnifera alcohol extract was found to be 1750 mg/kg body weight (BW) (p.o.) in albino mice.
- The acute LD50 for Ashwagandha extract (2% pure alkaloids) was found to be 465mg/kg BW in rats and 432 mg/kg BW in mice.

4 First aid measures

- 4.1 Description of first aid measures:
- General information: No special measures required.
 - After inhalation: Supply fresh air; consult doctor in case of complaints.
 - After skin contact: Generally the product does not irritate the skin.
 - After eye contact: Rinse opened eye for several minutes under running water.
 - After swallowing: If symptoms persist consult doctor.
- 4.2 Information for doctor:
- Most important symptoms and effects, both acute and delayed: No further relevant information available.
 - Indication of any immediate medical attention and special treatment needed
- 4.3 Indication of any immediate medical attention and special treatment needed
- no data available

5 Firefighting measures

- 5.1 Extinguishing media
- Suitable extinguishing agents: CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- 5.2 Special hazards arising from the substance or mixture
- Unusual Fire and Explosion Hazards: None known
- 5.3 Advice for firefighters
- Special Fire Fighting Procedures: Move container from fire area if it can be done without risk. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low area.
- Protection for fire-fighters: Boots, gloves, goggles.
- 5.4 Further information
- Flash Point: Not available.

Auto ignition Temperature: Not available.

Explosion Limits:

Lower: Not available.

Upper: Not available.

NFPA Rating: Not published.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections:

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

7.1 Handling:

· Precautions for safe handling: No special measures required.

· Information about fire - and explosion protection: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

· Storage:

· Requirements to be met by storerooms and receptacles: No special requirements.

· Information about storage in one common storage facility: Not required.

· Further information about storage conditions: None.

7.3 Specific end uses:

Apart from the uses mentioned in section 1 no other specific uses are stipulated

8 Exposure controls/personal protection

· Additional information about design of technical facilities: No further data; see item 7.

8.1 Control parameters

· Ingredients with limit values that require monitoring at the workplace: Not required.

· Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls

· Personal protective equipment:

· General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

· Respiratory protection: Not required.

· Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection: Not required.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties:

· Appearance:

Form: Powder

Colour: According to product specification

· Odour: Characteristic

· Odour threshold: Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gaseous): Product is not flammable.

· Ignition temperature:
Decomposition temperature: Not determined.
· Self-igniting: Not determined.
· Danger of explosion: Product does not present an explosion hazard.
· Explosion limits:
Lower: Not determined.
Upper: Not determined.
· Vapour pressure: Not applicable.
· Density at 20°C: 0,6 g/cm³
· Relative density Not determined.
· Vapour density Not applicable.
· Evaporation rate Not applicable.
· Solubility in / Miscibility with water: Not determined.
· Segregation coefficient (n-octanol/water): Not determined.
· Viscosity:
Dynamic: Not applicable.
Kinematic: Not applicable.
· Solvent content:
Organic solvents: 0,0 %
VOC (EC) 0,00 %
Solids content: 100,0 %
9.2 Other information:
· No further relevant information available.

10 Stability and reactivity

10.1 Reactivity: None known
10.2 Stability: Stable under ordinary conditions of use and storage.
Stability Note(s): Conditions of Instability: Excess heat, dust generation
10.3 Hazardous Polymerization: Has not been reported.
10.4 Conditions To Avoid: No dangerous reactions known under use of normal conditions. Avoid extreme heat.
10.5 Incompatibility – Materials to avoid: No dangerous reaction known with common products.
10.6 Hazardous Decomposition Products: No dangerous decomposition products known.
Decomposition Or Byproducts: No data available.

11 Toxicological information

11.1 Information on toxicological effects (source: ECHA 2022):
Toxicity to Animals (also see section 3.2.):
Acute Toxicity: oral:
In acute toxicity studies the LD50 of a Withania somnifera alcohol extract was found to be 1750 mg/kg body weight (BW) (p.o.) in albino mice.
The acute LD50 for Ashwagandha extract (2% pure alkaloids) was found to be 465mg/kg BW in rats and 432 mg/kg BW in mice.
Acute Toxicity: inhalation:
No data available.
Acute Toxicity: dermal:
No data available.
Acute Toxicity: other routes:
In a study, in which an alcohol extracts from the roots of Ashwagandha was used, showed that a single intraperitoneal injection of 1100 mg/kg BW of the extract in mice did not produce any deaths within 24 hours, but small increases led to mortality. The LD50 value was calculated as 1260 mg/kg BW.
Skin corrosion/irritation:
No irritant effect.
Serious eye damage/eye irritation:
No irritant effect.
Skin sensitization:
No sensitizing effects known.
Respiratory sensitization:
No data available.
Repeated dose toxicity: oral:
No data available.
Repeated dose toxicity: inhalation:
No data available.
Repeated dose toxicity: dermal:
No data available.
Repeated dose toxicity: other routes:
No data available.
Germ cell mutagenicity:
Genetic toxicity: in vitro:

No data available.

Genetic toxicity: in vivo:

No data available.

Carcinogenicity:

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Toxicity to reproduction:

No data available.

Specific target organ toxicity - single exposure:

No data available.

Specific target organ toxicity - repeated exposure:

No data available.

Aspiration hazard:

No data available.

Chronic Effects on Humans:

No data available.

Other Toxic Effects on Humans: Slightly hazardous in case of eye contact (irritant), of inhalation.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans: Not available.

Special Remarks on other Toxic Effects on Humans:

Acute Potential Health Effects: Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion: May be harmful if swallowed.

Skin: May be harmful if absorbed through skin. May cause skin irritation.

Eyes: May cause eye irritation.

Additional Information:

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

11.2 Special remarks:

No data available.

12 Ecological information

12.1 Ecotoxicity (source: ECHA 2021):

Aquatic toxicity:

Short-term toxicity to fish:

No data available.

Long-term toxicity to fish:

No data available.

Short-term toxicity to aquatic invertebrates:

No data available.

Long-term toxicity to aquatic invertebrates:

No data available.

Toxicity to aquatic algae and cyanobacteria:

No data available.

Toxicity to microorganisms:

No data available.

Toxicity to other aquatic organisms:

No data available.

Terrestrial toxicity:

Toxicity to soil macroorganisms except arthropods:

No data available.

Toxicity to terrestrial arthropods:

No data available.

Toxicity to terrestrial plants:

No data available.

Toxicity to soil microorganisms:

No data available.

12.2 Persistence and degradability:

Low persistence level and readily biodegradable.

12.3 Bioaccumulative potential:

None established.

12.4 Mobility in soil:

Low mobility in the soil.

12.5 Results of PBT and vPvB assessment:

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

13 Disposal considerations

13.1 Waste treatment methods

Do not pour into drains or waterways.

Proper waste management of the substance and/or its container must be determined in accordance with Directive 2008/98/EC.

13.2 Waste :

Waste management is carried out without endangering human health, without harming the environment and in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company. Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

13.3 Packaging:

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

14 Transport information

14.1 UN-Number: ADR/RID: -
IMDG: -
IATA: -

14.2 UN proper shipping name: ADR/RID: Not dangerous goods.
IMDG: Not dangerous goods.
IATA: Not dangerous goods.

14.3 Transport hazard class(es): ADR/RID: -
IMDG: -
IATA: -

14.4 Packing group: ADR/RID: -
IMDG: -
IATA: -

14.5 Environmental hazards: ADR/RID: no
IMDG: no
IATA: no

14.6 Special precautions for user: No special precautions needed.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: No data available.

15 Other Regulatory Information

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

15.2 Chemical Safety Assessment: A Chemical Safety Assessment has not been carried out.

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

16 Other information

GHS Classification and labelling information ECHA :

Classification of the substance or mixture:

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

This substance is not classified as dangerous according to Directive 67/548/EEC.

Label elements:

The product does not need to be labelled in accordance with EC directives or respective national laws

-> **self classification:**

Hazard Symbol / pictogram: **not applicable**

Signal word: **not applicable**

Hazard Statement: H320 Causes eye irritation
H335 May cause respiratory irritation.

Precautionary statement: P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P281 Use personal protective equipment as required

The information above 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 purposes. In no event shall supplier be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if supplier has been advised of the possibility of such damages.

· Abbreviations and acronyms:

ADN	EU Agreement concerning International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BLV	Biological limit value
CAS-No.	Chemical Abstract Service number
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
EC-No.	European Community number
EINECS	European Inventory of Existing Commercial Chemical Substances
EN	European Standard
EUH statement	CLP-specific Hazard statement
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
IATA	International Air Transport Association
ICAO	International Civil Aviation Organisation
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Reg.(EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
RRN	REACH Registration Number
vPvB	Very Persistent and Very Bioaccumulative
WGK	Water Hazard Class