

Technical Data Sheet

Product Name: Berberine Hydrochloride 97% Powder

Product Code: EZ891247a

1. Technical Data Sheet		
Chemical Name	Berberine Hydrochloride	
CAS Number	633-65-8	
Molecular Weight	371.81	
Molecular Formula	C ₂₀ H ₁₈ NO ₄ Cl	
Compliance (Food / Pharmacopoeia / FCC / Feed)	Food	
Source (Animal / Plant / Mineral / Petrochemical)	Plant	
Brief Introduction: Berberine is a naturally occurring yellow alkaloid in some plants. Berberine HCL is the native form combine with hydrogen chloride to make it more stable.		
Item	Standard	Analysis Method
Appearance, odor, and taste	Yellow powder, odorless, taste bitter.	Visual & Taste
Typical Analysis		
Identification		
(1) Color reaction A	Positive	CP2020
(2) Color reaction B	Positive	CP2020
(3) Color reaction C	Positive	CP2020
(4) IR	Corresponds to IR ref. spectrum	CP2020
Assay	≥97.0%	HPLC
Loss on drying	≤12.0%	105°C/5h
Residue on ignition	≤0.2%	CP2020
Bulk density	≥0.5g/ml	CP2020
Particle size	100% pass 80 mesh sieve	CP2020
Other alkaloids	Meet the requirements	CP2020
Heavy metals		
Total Heavy Metals	≤10 ppm	USP <233>
Lead	≤3.0 ppm	USP <233>
Arsenic	≤1.0 ppm	USP <233>
Cadmium	≤1.0 ppm	USP <233>
Mercury	≤0.1 ppm	USP <233>
Microorganism		
Total plate count	≤1,000 cfu/g	USP <61>
Molds & Yeasts	≤100 cfu/g	USP <61>
E. coli	Negative/10g	USP <62>

Salmonella	Negative/10g	USP <62>
Staphylococcus	Negative/10g	USP <62>
Storage & Shelf Life		
Package	25kg/drum	
Shelf Life	The shelf life for the product is 24 months from date of production. Use it as soon as possible once it is opened.	
Storage	Store in unopened original package under clean and dry condition, away from sunlight.	

2.Origin & Ingredient			
Country of origin of the product: China		Origin statement: available ☒	
This product is a pure material ☒		This product is a compound material ☐	
The product's composition is 100% Berberine Hydrochloride			
Animal origin	☐ bovine	Specific Source: /	
	☐ porcine	Specific Source : /	
	☐ ovine	Specific Source : /	
	☐ others:	Specific Source: /	
Synthetic	☐	Starting material:	Origin:
Biotechnological processing	☐ Catalysis By Enzymes	Name of Enzyme: / Sources of Enzymes : /	
	☐ Fermentation	Source of Medium: / Strain: /	
Botanical Origin	Botanical Name:	<i>Berberis aristata</i>	
	Part:	Bark from the Branches	
	Wild or Cultivated :	/	
	Country of Origin:	China	
	Solvent Used :	/	

3.Nutrition Data	
Nutritional Composition	☒ Per 100g ☐ Per Serving
☐ Energy (KJ) ☒ Energy (Kcal)	0kcal
Fat (g)	0
Carbohydrates (g)	0
Protein (g)	0
Sodium (mg)	0
Remarks: Nutrition Data Are Obtained By 3 rd Party Lab; Tested on A Yearly Basis	

4.Manufacture Details	
Manufacturer Name:	Enzymolab Biotech Co., Ltd
Address:	Tianmu Road, Laiyang Development District, Yantai, Shandong
Capacity of Production	200mt per year
Number of Employees in Production: 56	Number of Employees in QA / QC.: 8
Quality And Food Safety Management System Certificated by Accredited Authority. E.G.: ISO Series, GFSI Series HACCP GMP、CGMP FAMI-QS、GMP+	ISO9001 Series: ☐ ISO9001 ☐ ISO22000 ☐ ISO14001 ☐ ISO45000 GFSI Series: ☒ BRC ☐ FSSC22000 ☐ IFS ☐ SQF ☐ GMP ☐ HACCP ☐ FAMI-QS ☐ GMP+
Product Related Certificates	☐ HALAL ☐ KOSHER ☐ IP ☐ ORGANIC
Suitable For Vegan	☒ YES ☐ NO
We Confirm Above Mentioned Certificates or Related Statement And Keep Available ☒	

5.Process Quality and Food Safety		
Flow chart : This product specification has listed the detailed process flow chart of each step of the actual production process from raw material pretreatment to finished product warehousing, including possible additives, processing aids, steps to remove foreign matters, CCP, water used, compressed air etc.		Integrity flow chart available ☒
CCP In Place		
CCP info.	CL	Location in process
Foreign Body Control		
Have implemented control procedures for glass, fragile plastic materials ☒		
Pest Control		
Conducted by manufacturer: ☒		
by external contractor ☐ Name of contractor:		

Batch Number & Traceability	
Batch Size	500kgs
We confirm that we perform batch and traceability management on the whole process from raw material receiving, production process, storage, and transportation, by focusing on raw materials, semi-finished products, production processing and transportation, related records, and product labels. Take traceability exercise on an annual basis.	
Supply Chain Custody	
To ensure proper oversight and control of the supply chain in the production of supplement raw materials, it is essential to monitor and document every step, from farm, field, or ocean, through processing and final delivery to the customer. Below is a detailed breakdown of each stage, highlighting key links in the supply chain and the actions taken at each step: 1. Sourcing of Raw Materials 2. Transportation from Source 3. Receiving at Processing Facility 4. Processing & Transformation 5. Packaging and Labeling 6. Storage Before Distribution 7. Transportation to Customers 8. Post-Delivery & Customer Feedback 9. Continuous Improvement & Auditing	

6. Non-GMO Declaration		
	YES	NO
The product does not contain or consist of GMO	☐	☒
The product is not produced from GMO or not contain ingredients produced from GMO (irrespective of whether there is NDA or protein of GM origin in the final production)	☐	☒
This product is not produced by means of GM microorganism including precursor substances, e.g., with GMOs or Genetically Modified microorganisms processing aids (bacteria, yeast,).	☐	☒
This product is not produced with the help of enzymes, which were obtained from GMOs	☐	☒
Does the product contain any ingredients from animal?	☐	☒
If yes, are genetically modified crops contained in the feed for the animal?	☐	☒
We confirm that this product complies with regulations EC/1829/2003 and EC1830/2003 and keep non-GMO statement available.	☒	☐

7. Allergen Declaration

We have carefully reviewed this product according to EU Regulation 1169/2011 and modifications and confirm the following:

	Direct incorporation as a base raw material or in a derivative form (don't forget the carriers, the additives, and the processing aids)		CROSS CONTAMINATION					
			Presence on the production line		Presence on the production workshop		Presence on the production factory	
	Yes (Precise nature)	No	Yes (precise the nature)	No	Yes (precise the nature)	No	Yes (precise the nature)	No
Cereals containing gluten (1) and products thereof		N		N		N		N
Crustaceans and products thereof		N		N		N		N
Eggs and products thereof		N		N		N		N
Fish and products thereof (2)		N		N		N		N
Peanuts and products thereof		N		N		N		N
Soybeans and products thereof (3)		N		N		N		N
Milk and products thereof (including lactose) (4)		N		N		N		N
Nuts (5) or products thereof		N		N		N		N
Celery and products thereof		N		N		N		N
Mustard and products thereof		N		N		N		N
Sesame seeds and product thereof		N		N		N		N
Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10 mg/l expressed as SO ₂		N		N		N		N
Lupines and products		N		N		N		N

thereof								
Mollusc and product thereof		N		N		N		N
Cereals which contain gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised 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; Except: fish gelatine used as carrier for vitamin or carotenoid preparations, fish gelatine or Isinglass used as fining agent in beer and wine. 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. Except when used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages, lactitol. almond (<i>Amygdalus communis</i> L.) hazelnuts (<i>Corylus avellana</i>), walnut (<i>Juglans regia</i>), cashew (<i>Anacardium occidentale</i>), pecan nuts (<i>Carya illinoensis</i>), Brazil nut (<i>Bertholletia excelsa</i>), pistachio nut (<i>Pistacia vera</i>), macadamia nut and Queensland nut (<i>Macadamia terniflora</i>) and products thereof, except nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;								

8. non-Irradiation		
(According to EU directive 1999/2/EC & 1999/3/EC)		
This product has not been treated with ionising radiation	☐ YES	☒ NO
None of the raw materials we used for this product have been treated with ionising radiation.	☐ YES	☒ NO
We confirm above non-Irradiation statement is available	☒ YES	

10. Nanomaterial		
(According to EU Regulation (EU) No. 1363/2013)		
This product does not contain any nanomaterials as defined in EU food legislation	☐ YES	☒ NO
This product has not been made with nanotechnology	☐ YES	☒ NO
We confirm above non-Nanomaterial statement is available	☒ YES	

10. Residual Solvents	
(According to UE Directive 2009/32 modified by (UE)2010/59; EP5.4; USP476; ICH Q3C(R7))	
For this product following solvents are used during production process: Solvent A: max residual level:	☒ solvent used. ☐ solvent not used

We confirm solvent residual of this product complies with:	☒ EP 7.0 ☒ USP <476> ☒ ICH Q3C(R7) ☐ Directive 2010/59/EU ☐ NA
We confirm Solvent residual statement is available	☒ YES

11.Pesticide Residual (According to EC 396/2005; EP07; USP <561>)	
This product is of vegetable origin	☒ YES ☐ NO
We confirm pesticide residual of this product complies with:	☒ EC 396/2005 ☒ EP 07/2008 ☒ USP<561> ☐ N/A
Pesticide residual statement available	☒ YES

12.BSE/TSE Information (According to EU No. 2019/319; EP general chapter 5.2.8)	
Cattle, sheep, goats, and other animals naturally susceptible to infection with transmissible spongiform encephalopathy (TSE) agents, or those susceptible to infection through the oral route (excluding humans and non-human primates), are defined as "BSE-relevant animal species." Pigs and birds, however, are not naturally susceptible to infection via the oral route and, therefore, are not considered TSE-relevant species. Similarly, dogs, rabbits, and fish are also not classified as TSE-relevant animal species.	
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).	☐ YES ☒ NO ☐ NA
In the manufacturing of this product, there is not any raw or source material and /or reagent used that is of animal origin i.e., bovine, serum-albumin, enzymes, culture broths including those used to prepare working or master cell tanks.	☐ YES ☒ NO

Equipment/systems/tools use for processing or storage of the material do not come into contact at any time with materials of animal origin (e.g., components of media filler used to check such system).	☐ YES ☒ NO
The material is not purified by using solvents, chromatographic media or buffers that contain components of animal origin.	☐ YES ☒ NO
We confirm this product complies with:	☒ EU legislation 999/2001 & ☐ EP general chapter 5.2.8
We confirm BSE/TSE statement is available	☒ YES

13. Contaminants Information

(According to UE regulation NO.1881/2006 and NO.629/2008 as regards maximum levels for certain contaminants in foodstuff)

Aflatoxin B1 <5ppb Aflatoxins B1 + B2 + G1 + G2 <10ppb Ochratoxin A <15ppb	☒ YES ☐ NO ☐ NA
Melamine Free	☒ YES
Dioxins, Furans, Polychlorinated Biphenyls Free	☒ YES
For polycyclic aromatic hydrocarbons, in cocoa fiber, banana chips, food supplements and their preparations, dried herbs <i>and dried spices</i> . Maximum level of 10 µg/kg of benzo(a)pyrene 50 µg/kg for the sum of PAH4 (PAH4; benzo[a]pyrene, chrysene, Benz[a]anthracene and benzo[b]fluoranthene) in food supplements	☒ YES ☐ NO ☐ NA
We confirm this product complies with NO.1881/2006 and NO.629/2008 and keep compliance statement available	☒ YES

14. WADA Statement

We confirm that none of the products manufactured or stored within our facility contain any prohormones, stimulants, steroids, or other substances listed on the current WADA (World Anti-Doping Agency) list.

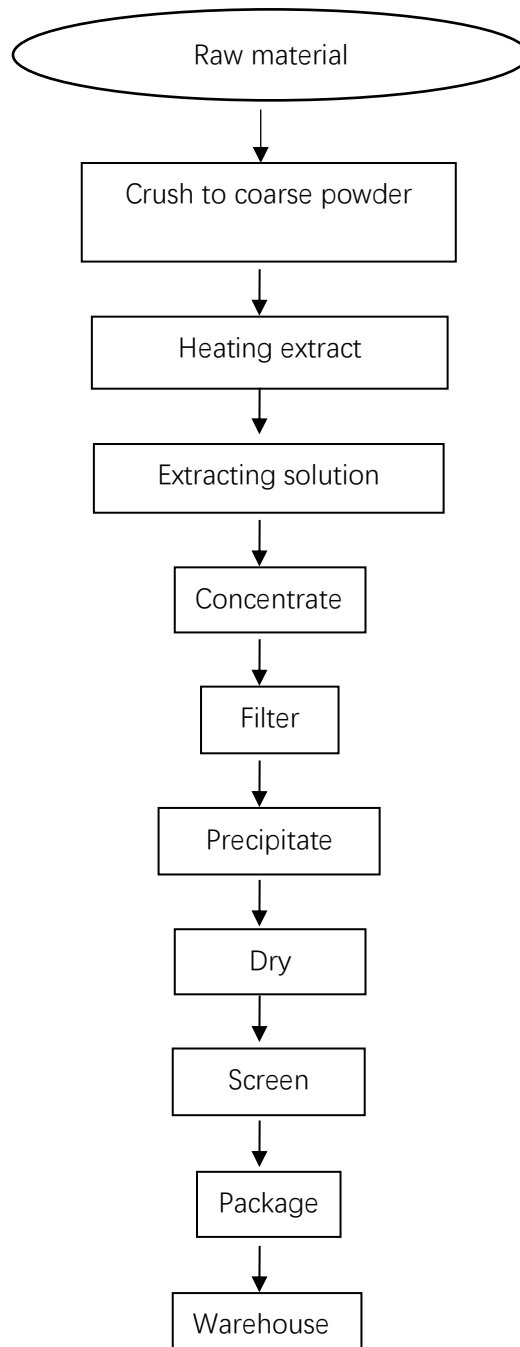
15. ETO Free Statement

We hereby confirm that ethylene oxide (ETO), 2-chloroethanol, or any other chemical sterilizing agents are not used during the manufacturing, storage, or transportation of our products.

16. Other Statements

We confirm Nitrates of this product complies with EU No 1258/2011	☒ YES ☐ NO ☐ NA
We confirm Mycotoxins / Aflatoxins of this product complies with EU No 165/2010	☒ YES ☐ NO ☐ NA
We confirm 3-MCPD of this product complies with EU No. 2020/1322	☒ YES ☐ NO ☐ NA
We confirm Pyrrolizidine alkaloids of this product complies with Regulation (EU) 2020/2040	☒ YES ☐ NO ☐ NA

Flow Chart



Material Safety Data Sheet

According to Regulation (EC) No. 1907/2006 Version 1.0

Revision Date 30.08.2023

Print Date 25.09.2023

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION

Product Name: BerGluco™ Berberine Hydrochloride

2. HAZARDS IDENTIFICATION

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms: BERBERINE HCl; BERBERINE CHLORIDE HYDRATE; 6-DIHYDRO-9,10-DIMETHOXY-BENZO[G]-1,3-BENZODIOXOLO[5,6-A] QUINOLIZI NIUM, CHLORIDE; BERBERINE CHLORIDE; BERBERINE; BERBERINE HYDROCHLORIDE N-HYDRATE

Formula: $C_{20}H_{18}ClNO_4$

Molecular Weight: 371.81 g/mol

CAS No.: 633-65-8

4. FIRST AID MEASURES

Eye Contact: No known effect on eye contact, rinse with water for a few minutes.

Skin Contact:

After contact with skin, wash immediately with plenty of water. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases, and groin. Cover the irritated skin with an emollient. If irritation persists, seek medical attention. Wash contaminated clothing before reusing.

Serious Skin Contact: Not available.

Inhalation: Allow the victim to rest in a well-ventilated area. Seek immediate medical attention.

Serious Inhalation: Not available.

Ingestion:



Do not induce vomiting. Loosen tight clothing such as a collar, tie, belt, or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention.

Serious Ingestion: Not available.

5. FIRE AND EXPLOSION DATA

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: Not available.

Flash Points: Not available.

Flammable Limits: Not available.

Products of Combustion: Not available.

Fire Hazards in Presence of Various Substances: Not available.

Explosion Hazards in Presence of Various Substances:

Risks of explosion of the product in presence of mechanical impact: Not available. Risks of explosion of the product in presence of static discharge: Not available.

Fire Fighting Media and Instructions:

SMALL FIRE: Use DRY chemical powder.

LARGE FIRE: Use water spray, fog, or foam. Do not use water jet.

Special Remarks on Fire Hazards: Not available.

Special Remarks on Explosion Hazards: Not available.

6. ACCIDENTAL RELEASE MEASURES

Small Spill:

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:

Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

7. HANDLING AND STORAGE Precautions:

Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not breathe dust.

Storage:



Keep container dry. Keep in a cool place. Ground all equipment containing material. Keep container tightly closed. Keep in a cool, well-ventilated place. Combustible materials should be stored away from extreme heat and away from strong oxidizing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls:

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume, or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection: Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state and appearance: Solid Powder

Odor: Characteristic.

Taste: Not available.

Molecular Weight: 371.81

Color: Yellow

Boiling Point: No data

Melting Point: Not available.

Critical Temperature: Not available.

Specific Gravity: Not available.

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water.

Solubility: 1mg/ml at 25C°

10. STABILITY AND REACTIVITY DATA

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Not available.

Incompatibility with various substances: Not available.

Corrosivity: Not available.

Special Remarks on Reactivity: Not available.

Special Remarks on Corrosivity: Not available.

Polymerization: No.

11. TOXICOLOGICAL INFORMATION

Routes of Entry: Absorbed through skin. Eye contact. Inhalation. Ingestion.

Toxicity to Animals:

LD50: 295.86mg/kg. (oral mouse)

LC50: Not available.

Chronic Effects on Humans: Not available.

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

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: Not available.

12. ECOLOGICAL INFORMATION

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: Not available.

Special Remarks on the Products of Biodegradation: Not available.



13. DISPOSAL CONSIDERATIONS

Waste Disposal:

Waste must be disposed of in accordance with federal, state, and local environmental control regulations

14. TRANSPORT INFORMATION

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

15. OTHER REGULATORY INFORMATION

Federal and State Regulations: No products were found.

Other Regulations: Not available.

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC): This product is not classified according to the EU regulations.

HMIS (U.S.A.):

Health Hazard: 1

Fire Hazard: 1 Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 1 Flammability: 1 Reactivity: 0 Specific hazard:

Protective Equipment:

Gloves.

Lab coat.

Dust respirator. Be sure to use an approved/certified respirator or equivalent. Safety glasses.

16. Other Information

References: Not available.

Other Special Considerations: Not available.

Created: 10/09/2010 05:37 PM

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 purposes.