PRODUCT NAME	D-Biotin

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/EC & 1999/3/EC concerning foods and food ingredients treated with ionizing radiation

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 conformed to the EU legislation 999/2001

PACKAGING Statement

We hereby certify that the packaging 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, based on our actual knowledge of production process, raw materials and equipment used potential pesticide residues in the above-mentioned product comply with the following raw and regulation:

☑ Regulation (EC)None. 396/2005.

☑ EP 07/2008:20813

☑ USP <561>

☐ others: N/A

RESIDUAL SOLVENT Statement

We hereby certify that the product meets with:

☑Directive 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.

☑ EP 5.4

☑USP <476>

☑ICH Q3C(R7)

CONTAMINANT Statement

浙江圣达生物药业股份有限公司
ZHEJIANG SHENGDA
BIO-PHARM CO.,LTD.

This is to certify that the product meets with:

- REGULATION (EC) No- 1881/2006 an subsequent amendments as concerns the maximum level admitted of the following contaminants:
  - Aflatoxin B1 <5ppb
  - Aflatoxins B1 + B2 + G1 + G2 <10ppb
  - Ochratoxin A <15ppb
  - Melamine
- REGULATION (EU)2015/1933 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 (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.

GMO

Not derived from Genetically Modified Organism (G.M.O.) – According to regulations 1829/2003/EC and 1830/2003/EC concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and any amending legislation

Allergens

We have carefully reviewed this product according to According Directive 2003/89/EC, 2005/68/EC,2007/68/CE amending Annexe IIIbis of Directive 2000/13/CE as regards indication of ingredients present in foodstuffs 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

浙江圣达生物药业股份有限公司
ZHEJIANG SHENGDA BIO-PHARM CO.,LTD.

	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 SO2		N		N		N		N
Lupines and products thereof		N		N		N		N
Mollusc and product thereof		N		N		N		N

(1) 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;

(2) Except: fish gelatine used as carrier for vitamin or carotenoid preparations, fish gelatine or Isinglass used as fining agent in beer and wine;

(3) Except fully refined soybean oil and fat, natural mixed tocopheols (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 producted 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 (Amydalus communis L.) hazelnuts (Corylus avellana), walnut (Juglans regia), cashew (Anacardium occidentale), pecan nuts (Carya illinaiesis), 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 bereverages;

Company: Zhejiang Shengda Bio-Pharm Co., Ltd.

Date: July 15, 2020

(Sign and Stamp)

徐文勉

浙江圣达生物药业股份有限公司
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