

FICHA TÉCNICA - DATA SHEET

INFORMACION GENERAL - GENERAL INFORMATION

NOMBRE DEL PRODUCTO / PRODUCT NAME	ARROZ ROJO EXTRACTO SECO
NOMBRE EN LATIN / BOTANICAL NAME	MONASCUS PURPUREUS
ORIGEN- ORIGIN	CHINA
PARTE USADA DE LA PLANTA / PLANT PART USED	LEVADURA FERMENTADA - FERMENTED
EXCIPIENTE / EXCIPIENTS	MALTODEXTRIN < 10%
SOLVENTE DE EXTRACCION / EXTRACTION SOLVENT	AGUA - ETANOL / WATER- ETHANOL

TEST FISICO - PHYSICAL TESTS

ESPECIFICACIONES / SPECIFICATIONS *	STANDARD	METODO / METHOD
ASPECTO / APPEARANCE	POLVO MARRON ROJO – BROWN RED POWDER	VISUAL / VISUAL
OLOR / ODOUR	CARACTERISTICO / CHARACTERISTIC	OLFATIVO / OLFACTORY
GUSTO / TASTE	CARACTERISTICO / CHARACTERISTIC	GUSTATIVO / OF TASTE
TAMAÑO/ SIZE	100 through 80 MESH	USP 36-786
DENSIDAD RELATIVA / RELATIVE DENSITY	40-60g/100ml	Eur.Ph.7.0-(2.9.34)
SOLUBILIDAD / SOLUBILITY	MODERADAMENTE SOLUBLE -PARTIALLY SOLUBLE	
TOTAL ASH	≤ 10 %	Eu. Pharm.7.0 (2.4.16)
PERDIDA POR DESECACION- LOSS ON DRYING	≤ 5 %	Eu. Pharm.7.0 (2.8.17)

** Las características organolépticas de los extractos secos pueden sufrir variaciones de un lote a otro debido a la procedencia vegetal de la materia prima utilizada para su elaboración, fecha de cosecha, zona de procedencia o clima durante su cultivo, no afectando en ningún caso a las propiedades ni a la calidad del mismo. (Color, olor,sabor, humedad, etc...)- * The organoleptic characteristics of dried extracts may change from batch to batch due to the vegetable origin of the raw material used for processing, the date of harvest, the processing area or the climate during the crop, not affecting in any case to the Properties neither to the quality of the extract. (Color, smell, taste, humidity, and so on ...)*

TEST QUIMICO - CHEMICAL TESTS

ESPECIFICACIONES / SPECIFICATIONS	STANDARD	METODO / METHOD
TITULO / TITLE	≥ 5% MONACOLIN K	HPLC
RATIO	20 : 1	
RESIDUOS SOLVENTES / RESIDUAL SOLVENTS	Meet Eur.Ph.7.0 <5.4>	Eu. Pharm.7.0 (2.4.24)
METALES PESADOS / HEAVY METALS		
As	<2ppm	Eu. Pharm.7.0 (2.2.58) ICP- MS
Pb	<3ppm	Eu. Pharm.7.0 (2.2.58) ICP- MS
Cd	<1ppm	Eu. Pharm.7.0 (2.2.58) ICP- MS
Hg	<0,1ppm	Eu. Pharm.7.0 (2.2.58) ICP- MS
AFLATOXIN B1- B1,B2,G1,G2	<2ppb-<4ppb	BP 2015
PESTICIDES	USP 36-561	USP 36-561 / Conforme Reg (EC) 396/2005
BENZOPYRENE	≤10 ppb GC/MS	Eu. 2015/1933
PAH's	≤50 ppb	Eu. 2015/1933
CITRININA	≤ 2000 ppb	REG. (EU) No 212/2014
NON IRRADIATED	≤ 700	EN13751:2002- PSL

ANALISIS MICROBIOLÓGICO - MICROBIOLOGICAL ANALYSIS

ESPECIFICACIONES / SPECIFICATIONS	STANDARD	METODO / METHOD
AEROBIOS TOTALES / TOTAL COUNT	<10.000ufc/g	USP 36-61
MOHOS Y LEVADURAS / MOLD AND YEAST	<1000ufc/g	USP 36-61
P.AUREGINOSA	AUSENCIA- NEGATIVE	USP 34-62
STAPHYLOCOCCUS	AUSENCIA- NEGATIVE	USP 34-62
ESCHERICHIA COLI	AUSENCIA- NEGATIVE	USP 36-62
SALMONELLA	AUSENCIA- NEGATIVE	USP 36-62

OTRAS INFORMACIONES - OTHER INFORMATIONS

PRODUCTO LIBRE OGM CONFORME A LA DIR.CE 1829/2003 y 1830/2003).-GMO FREE ACCORDING TO DIR.CE 1829/2003 y 1830/2003).	CONFORME- CONFORM
PRODUCTO LIBRE DE ALERGENOS CONFORME A LA REGULATION (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011- ALLERGENS FREE ACCORDING TO REGULATION (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011	CONFORME- CONFORM
LIBRE DE BSE/TSE (en acuerdo con EEC99/742/EC y 97/534/EC) -BSE/TSE FREE (according to EEC99/742/EC and 97/534/EC)	CONFORME- CONFORM
CADUCIDAD / SHELF LIFE	3 AÑOS / 3 YEARS
ALMACENAMIENTO / STORAGE	Conservar en lugar fresco y oscuro, alejado de la luz. Conservar a temperatura no superior a 30°C / Store in a cool dry area, keep away from strong direct light. Store at temperature not more than 30°C.
EMBALAJE / PACKAGING	Bolsa alimentaria / Alimentary bags

TODOS LOS DATOS INDICADOS SON PROCEDENTES DE NUESTRO PROVEEDOR/FABRICANTE - ALL DATA INDICATED ARE FROM OUR SUPPLIER / MANUFACTURER

LA INFORMACION ARRIBA ESPECIFICADA NO EXIME EN CUALQUIER CASO AL DESTINATARIO DE LA MERCANCÍA DE LA OBLIGACION DE IDENTIFICAR Y CONTROLAR EL PRODUCTO EN RELACION AL EMPLEO PREVISTO Y AJUSTAR EN TODO MOMENTO SU USO/DESTINO A LA LEGISLACIÓN VIGENTE EN CADA CASO.

EL USO/DESTINO FINAL DE LA MATERIA PRIMA ES DESCONOCIDO POR COREXNAT S.L EN EL MOMENTO DE LA OPERACIÓN COMERCIAL
- THE ABOVE SPECIFIED INFORMATION DOES NOT EXEMPT IN ANY CASE TO THE MERCHANT ADVERTISER THE OBLIGATION TO IDENTIFY AND CONTROL THE PRODUCT IN RELATION TO THE INTENDED USE AND TO ADJUST AT ALL TIMES HIS USE / DESTINATION TO THE LEGISLATION IN EACH CASE.

THE USE / FINAL DESTINATION OF THE RAW MATERIAL IS UNKNOWN BY COREXNAT S.L AT THE TIME OF THE COMMERCIAL OPERATION

CERTIFICADO EN FICHA TECNICA CONFORME SIN FIRMA / CERTIFICATE OR TECHNICAL DATA SHEET COMPLY ALSO NOT SIGNED

ALLERGEN STATEMENT

Designation: MONASCUS PURPUREUS EXTRACT

For the major allergens mentioned below, please indicate the presence or the possibility of the presence in the supplied ingredient.

Contains allergens which have to be labelled according to the above mentioned regulations:	+	Comment
Does not contain allergens which have to be labelled according to the above mentioned regulations:	-	
Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof	-	
Crustaceans and products thereof	-	
Eggs and products thereof	-	
Fish and products thereof	-	
Peanuts and products thereof	-	
Soybeans and products thereof	-	
Milk and products thereof (including lactose)	-	
Nuts i.e. Almond, Hazelnut, Walnut, Cashew, Pecan nut, Brazil nut, Pistachio nut, Macadamia nut and Queensland nut and products thereof	-	
Celery and products thereof	-	
Mustard and products thereof	-	
Sesame seeds and products thereof	-	
Sulphur dioxide and sulphite at concentrations of more than 10 mg/kg or 10 mg/l expressed as SO ₂	-	
Lupine and products thereof	-	
Molluscs and products thereof	-	

REGULATION (EU) No 1169/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 25 October 2011

The product contains other allergens: yes no

If yes, please indicate: _____

Material Safety Data Sheet

1. Identification of substance:

- Product details: Monascus purpureus extract
- Trade name: · Monascus purpureus extract

2. Composition/Data on components:

- Chemical characterization: natural product, botanical extract powder
- Description: brown red powder
- Dangerous components: no.

3. Hazards identification

Hazard description:

Material may be irritating to the mucous membranes and upper respiratory tract.

May be harmful by inhalation, ingestion or skin absorption

May cause eyes, skin, or respiratory system irritation

The toxicological properties of this compound have not been fully evaluated.

· Information pertaining to particular dangers for man and environment: not applicable

· Classification system:

The classification was made according to the latest editions of the EU-lists, and expanded upon from company and literature data

4. First aid measures

- General information: no special measures required.
- After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact: immediately wash skin with soap and plenty of water
- After eye contact: Rinse opened eye for several minutes under running water.
- After swallowing: if symptoms persist consult doctor.

5. Fire fighting measures

- Suitable extinguishing agents:
CO₂, extinguishing powder or water spray. Fight larger fires with water spray of alcohol resistant foam.
- Protective equipment: No special measures required.

6. Accidental release measures

- Measures for environmental protection: No special measures required.
- Measures for cleaning/collection:
Pick up mechanically avoiding causing a stir.
- Additional information: No dangerous substances are released.

7. Handling and storage

- Information for safe handling: No any effect.
- Information about protection against explosions and firms:
No special measures required.
- Storage: requirements to be met by storerooms and receptacles:
Keep container dry and sealed well
- Information about storage in one common storage facility: Not required.
- Further information about storage conditions: None.
- Storage class: no special requirement.

8. Exposure controls and personal protection

Additional information about design of technical systems:

No further data; see item 7.

- Components with limit values that require monitoring at the workplace:
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- Addition information:
The lists that were valid during the creation were used as basis.
- Personal protective equipment: Lab coat
- Breathing equipment: common mask.
- Protection of hands: Latex disposable gloves
- Eye protection: Safety glasses.

9. Physical and chemical properties:

- Form: powder or granule
- Odor: characteristic
- Active ingredients / extract ratio: $\geq 5\%$ Monacolin K
- Material: extract from 100% natural material
- Moisture: not more than 5.0%

10. Stability and reactivity

Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications. Material to avoid: strong oxidizing agents

- Dangerous reactions: No dangerous reactions known.
- Dangerous products of decomposition:
Dangerous decomposition products known. Carbon dioxide, carbon monoxide

11. Toxicological information

· Additional toxicological information:

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines of preparations as issued in the latest version: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12. Ecological information:

- General notes: Not known to be hazardous to water.

13. Transport information:

- ADR/RID class: can be by sea or by air

14. Other information:

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.

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